

RE Neoni cs meta-anal ysi s (2)

From: Kei gwi n, Ri chard [Kei gwi n. Ri chard@epa. gov]
Sent: Tuesday, January 27, 2015 3:38 PM
To: Bartuska, Ann - OSEC; Guilaran, Yu-Ti ng; Hackett, Kevin; Jones, Jim
Cc: Cep, Melinda -OSEC; Kuni cki s, Sheryl - OSEC; Col lantes, Margari ta; Brady, Donald; Housenger, Jack
Subject: RE: Neoni cs meta-anal ysi s

Ann--

Yu-Ting asked me to follow-up on this question. We would very much like to consider the information provided as part of the official record for the re-evaluation. With that in mind, I think it would be helpful if we could get a more official transmission (I think, for example, that the document is marked draft). Even though the public comment period is now closed, we can and will consider the information provided and we can still add it to the official record.

Hope that helps answer your questions.

--Rick

-----Original Message-----

From: Bartuska, Ann - OSEC [mail to: Ann.Bartuska@osec.usda.gov]
Sent: Tuesday, January 27, 2015 2:41 PM
To: Guilaran, Yu-Ting; Keigwin, Richard; Hackett, Kevin; Jones, Jim
Cc: Cep, Melinda -OSEC; Kuni cki s, Sheryl - OSEC; Col lantes, Margari ta; Brady, Donald; Housenger, Jack
Subject: RE: Neoni cs meta-anal ysi s

Yu-Ting, realizing that I sent this informally due to the discussion our office had been having with Jim and Rick, will this become part of the official record of Notice and Comment, or does it have to be sent officially.
Thanks, Ann

Ann M. Bartuska, PhD
Deputy Under Secretary for Research,
Education and Economics
USDA
202-720-1542

-----Original Message-----

From: Guilaran, Yu-Ting [mail to: Guilaran.Yu-Ting@epa.gov]
Sent: Tuesday, January 27, 2015 2:37 PM
To: Bartuska, Ann - OSEC; Keigwin, Richard; Hackett, Kevin; Jones, Jim
Cc: Cep, Melinda -OSEC; Kuni cki s, Sheryl - OSEC; Col lantes, Margari ta; Brady, Donald; Housenger, Jack
Subject: RE: Neoni cs meta-anal ysi s

Thanks Ann. We will look through this and follow up as needed.

Regards,

Yu-Ting Guilaran, P.E.
Director

Biological and Economic Analysis Division (BEAD) Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
(tel) 703 308 0052
(fax) 703 308 8091
Mail code 7503P

RE Neonic meta-analysis (2)

Room number PY S9723

-----Original Message-----

From: Bartuska, Ann - OSEC [mailto:Ann.Bartuska@osec.usda.gov]
Sent: Tuesday, January 27, 2015 11:03 AM
To: Keigwin, Richard; Hackett, Kevin; Jones, Jim
Cc: Cep, Melinda -OSEC; Kuni ckis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting
Subject: RE: Neonic meta-analysis

All, Attached are comments from ARS/USDA. Thanks for giving us time to provide these.

Regards, Ann

Ann M. Bartuska, PhD
Deputy Under Secretary for Research,
Education and Economics
USDA
202-720-1542

-----Original Message-----

From: Keigwin, Richard [mailto:Keigwin.Richard@epa.gov]
Sent: Monday, January 26, 2015 6:58 PM
To: Hackett, Kevin; Jones, Jim; Bartuska, Ann - OSEC
Cc: Cep, Melinda -OSEC; Kuni ckis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting
Subject: Re: Neonic meta-analysis

Kevin--

I wanted to follow-up on your earlier note. Does USDA have any feedback on the analysis we issued for public comment?

--Rick

Rick Keigwin
Director, Pesticide Re-evaluation Division Office of Pesticide Programs US
Environmental Protection Agency

From: Hackett, Kevin <Kevin.Hackett@ARS.USDA.GOV>
Sent: Friday, December 12, 2014 7:55 AM
To: Jones, Jim; Bartuska, Ann - OSEC
Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kuni ckis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting
Subject: RE: Neonic meta-analysis

Jim, We can submit some comments within 30 days. If you are interested in the analysis we are just embarking on, we can provide that in a year, if that would also be of use. Kevin

Kevin J. Hackett, Ph.D.
Senior National Program Leader
USDA/Agricultural Research Service
5601 Sunnyside Ave, 4-2222
Beltsville, MD 20705-5139
301-504-4680 (office)
301-504-6191 (fax)
Kevin.Hackett@ars.usda.gov

RE Neonics meta-analysis (2)

-----Original Message-----

From: Jones, Jim [mailto:Jones.Jim@epa.gov]
Sent: Friday, December 12, 2014 7:40 AM
To: Bartuska, Ann - OSEC
Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kuniacki, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting; Hackett, Kevin
Subject: Re: Neonics meta-analysis

Ann, we won't be formally extending the comment period. That being said we will give full consideration to the analysis USDA is working on. It would be much appreciated if it could be submitted within 30 days. Thx

Jim Jones

Assistant Administrator

Office of Chemical Safety and Pollution Prevention Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Original Message

From: Bartuska, Ann - OSEC
Sent: Thursday, December 11, 2014 1:11 PM
To: Jones, Jim
Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kuniacki, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting; Hackett, Kevin
Subject: Re: Neonics meta-analysis

Jim, our folks could get a response together with a 30 day extension; the more though meta-analysis will take a year as it will include plumbing unpublished results. Ann

Dr. Ann M. Bartuska

Deputy Under Secretary for

Research, Education and Economics

USDA

202-720-1542

> On Dec 10, 2014, at 11:57 AM, "Jones, Jim" <Jones.Jim@epa.gov> wrote:

>

> Ann, I think a conference call on the meta analysis would be great. Rick can organize the key players in the Pesticides Program.

>

> On the second issue can you let me know when your data is expected to be submitted to us on soybean seed efficacy? Thx

>

> -----Original Message-----

> From: Bartuska, Ann - OSEC [mailto:Ann.Bartuska@osec.usda.gov]

> Sent: Wednesday, December 10, 2014 10:36 AM

> To: Jones, Jim

> Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kuniacki, Sheryl - OSEC

> Subject: Neonics meta-analysis

>

> Jim, If you recall, this was the last point of discussion we had with you last week. As it turns out, I got a message from Kevin Hackett shortly after, that a team of ARS scientists are doing this exact thing as part of their revised 5 year research plan. Even better, David Epstein, OPMP has a bunch of data that they gathered and is going to work with Tom Sappington (ARS, Ames).

>

> I wanted you to be aware of this activity; happy to set up a conference call with your staff to discuss.

>

> I understand the public comment period on the recent neonictinoids analysis closes Dec 22. Because it would be of use to EPA's risk assessment, I am requesting EPA to extend its public comment period on their recent analysis of

RE Neonics meta-analysis (2)

neonic efficacy and soybeans. The ARS analyses could significantly contribute to your findings and it seems to be advantageous to demonstrate interagency collaboration. In a perfect world, an extension of a year would give the scientists time to fully analyze studies and data, but any extension would be helpful.

>

> Thank you for your consideration of this request. Ann

>

> Dr. Ann M. Bartuska

> Deputy Under Secretary for

> Research, Education and Economics

> USDA

> 202-720-1542

>

>

>

>

>

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Jean

From: Myers, Clayton [<mailto:Myers.Clayton@epa.gov>]
Sent: Wednesday, June 25, 2014 10:41 AM
To: Epstein, David
Cc: Guilaran, Yu-Ting; Jones, Arnet; Kiely, Timothy
Subject: Soybean information . . .

Dave,

In light of our recent conversation on information to inform BEAD's soybean benefit assessment for neonic. seed treatments, we wanted to get back with you asap. The information you requested from the North Central IPM center is precisely the type of information that would be helpful. In particular, you had mentioned in our prior meeting that there may be unpublished data that addresses the yield protection benefits for soybeans from specific pests or in specific regions. Also, given our discussion, it would be helpful to have specific information from the southern U.S. that addresses their high pest pressure and/or unique pests of concern (in terms of effects on soybean yield). In looking back at what you provided from Gore et al., they listed some tables from a yield study they did comparing neonic. seed treatments with fungicide against fungicide alone. If there is a paper or draft publication of that work, I'd like to see more on their methods and what their controls and comparisons were. Any additional data they have on soybean yield would be helpful. We have no additional specific questions beyond what you have already shared with the NC IPM center and discussed with us.

Clayton T. Myers, Ph.D
Entomologist/Biologist
U.S. Environmental Protection Agency
Office of Pesticide Programs

From: <Epstein>, David <David.Epstein@ARS.USDA.GOV>
Date: Wednesday, June 25, 2014 11:12 AM
To: "Haley, Jean Ann" <jahaley@illinois.edu>, lynnae jess <jess@cns.msu.edu>, Susan Ratcliffe <sratclif@illinois.edu>, "Olsen, Larry" <olsenl@cns.msu.edu>
Subject: EPA input for survey on seed treatments

Folks,

Below, is an email from Clayton Myers of EPA BEAD regarding our prior discussions of seed treatments and an EPA request for benefits information from the research community.

Sue, We will want to reach out to the other Center directors (see Clayton request for info from Southern States, below) once we (Ms. Jean) have (has) crafted some survey questions. We do want to restrict this call for information to the research community. Thanks.

Dave

From: Ratcliffe, Susan T [<mailto:sratclif@illinois.edu>]
Sent: Thursday, June 26, 2014 10:18 AM

From: [Keigwin, Richard](#)
To: [Kunickis, Sheryl - OSEC](#)
Subject: RE: Soybean benefits - USDA Comments
Date: Monday, April 06, 2015 4:34:39 PM

Thanks

Rick Keigwin
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs
US Environmental Protection Agency

Sent from my Windows Phone

From: [Kunickis, Sheryl - OSEC](#)
Sent: 4/6/2015 1:39 PM
To: [Keigwin, Richard](#)
Subject: RE: Soybean benefits - USDA Comments

Rick,
Attached are USDA's public comments on the EPA's Benefits of Neonicotinoid Seed Treatment to Soybean Production. Please let me know if there are questions. Again, thanks for your patience.

Sheryl

Sheryl H. Kunickis, Ph.D.
Director
USDA Office of Pest Management Policy
1400 Independence Ave., SW
Room 3871-South Building, MS-0314
Washington, D.C. 20250-0314

(202) 720-5375 Office
[REDACTED] Cell
sheryl.kunickis@osec.usda.gov

-----Original Message-----

From: Keigwin, Richard [mailto:Keigwin.Richard@epa.gov]
Sent: Thursday, April 02, 2015 7:54 AM
To: Kunickis, Sheryl - OSEC
Subject: RE: Soybean benefits

You can send them to me. Email is fine. We'll get them added to the docket.
No worries. Thanks!

Personal privacy information

From: [Keigwin, Richard](#)
To: [Kunickis, Sheryl](#)
Subject: RE: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.
Date: Tuesday, March 25, 2014 11:39:31 AM

Yes. I know that they cite some ARS studies. Jim heard about some of these studies when he attended the American Honey Producers Association meeting in San Antonio earlier this year; they definitely peaked his interest.

From: Kunickis, Sheryl <Sheryl.Kunickis@osec.usda.gov>
Sent: Tuesday, March 25, 2014 11:25 AM
To: Keigwin, Richard
Subject: Re: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.

Just finished. Meeting was with Under Secretary and other USDA leadership and staff. They brought all enviro groups-wow. They are heading to Hill to brief them and will be at a reception tonight. Big issues include residual in the soil and issues with water. Also, concern there are no benefits. Epstein was also there and can add more. Let's visit when you get back. Want to hear results of trip. Sad to hear of the losses. Lots to discuss!

Sheryl

From: Keigwin, Richard [mailto:Keigwin.Richard@epa.gov]
Sent: Tuesday, March 25, 2014 11:17 AM
To: Kunickis, Sheryl
Subject: FW: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.

Did you happen to participate in this meeting? I'd be curious to hear how it went.

Don and I are out in California. Had a meeting with the beekeepers yesterday. Very eye opening. Good conversation with some almond growers as well. I'll fill you in when I'm back in the office.

From: Steeger, Thomas
Sent: Tuesday, March 25, 2014 8:29 AM
To: Brady, Donald; Pease, Anita
Cc: Keigwin, Richard; Rossi, Lois
Subject: RE: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.

Center for Food Safety and Chris Krupke are meeting with USDA Chief Scientist Woteki at 9 am today. Dave Goulson, a researcher from the UK, is visiting as well. Dave was one of the coauthors on the study examining effects of neonics to bumblebees, and he has authored a review of neonic-related studies.

From: Brady, Donald
Sent: Monday, March 24, 2014 9:58 PM
To: Steeger, Thomas; Pease, Anita
Subject: Fw: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.

From: Keigwin, Richard
Sent: Monday, March 24, 2014 6:39:54 PM
To: Monell, Marty; Jordan, William; Rossi, Lois; Brady, Donald; Guilaran, Yu-Ting
Subject: FW: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.

fyi. I haven't read this yet.

From: Scheltema, Christina
Sent: Monday, March 24, 2014 3:21 PM
To: Keigwin, Richard
Subject: FW: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.

FYI .don't want you to get stung.

From: Kim Flottum [mailto:Kim@BeeCulture.com]
Sent: Monday, March 24, 2014 4:12 PM
To: Scheltema, Christina
Subject: CATCH THE BUZZ - Costs Out weigh Neonic Benefits. Study.

This ezine is also available online at <http://home.ezezone.com/1636/1636-2014.03.24.15.11.archive.html>

CATCH THE BUZZ

Study Reveals that Costs Outweigh Benefits of Toxic Insecticides Implicated in Bee Kills

Center for Food Safety today released a [scientific literature review](#) which reveals that neonicotinoid insecticide seed treatments offer little benefit, do not increase crop yields, and cause widespread environmental and economic damage. In particular, neonicotinoids have been implicated in bee population declines and colony collapse. While some fear that crop yields will suffer without the use of neonicotinoids, the study released today demonstrates that their benefits do not outweigh the costs.

The authors examined 19 peer-reviewed studies of the relationship between neonicotinoid treatments and actual yields of major U.S. crops. Eight studies found that neonicotinoid treatments did not provide any significant yield benefit, while 11 studies showed inconsistent

benefits. The studies corroborate evidence from European countries that were able to maintain crop yields even after neonicotinoid bans. The review cites the Environmental Protection Agency (EPA) for failure to conduct a thorough cost-benefit analysis and calls on EPA to suspend seed treatment product registrations.

"The environmental and economic costs of pesticide seed treatments are well-known. What we learned in our thorough analysis of the peer-reviewed science is that their claimed crop yield benefit is largely illusory, making their costs all the more tragic," said Peter Jenkins, co-author of the report and consulting attorney for Center for Food Safety.

Read the report [HERE](#).

Seeds of commercial crops in the U.S., particularly corn and soybeans, are widely treated with neonicotinoid pesticides, ostensibly to protect emerging seedlings from pests and thus improve yields. Almost all of the corn seed and approximately half of the soybeans in the U.S. are treated with neonicotinoids.

Neonicotinoids are a class of pesticides known to have acute and chronic effects on honey bees and other pollinator species and are considered a significant negative contributor to pollinator health. Neonicotinoid pesticides are also slow to break down, so they can build up in areas where they are applied. They contaminate surface water, ground water, and soil, endangering not only pollinators, but also other beneficial species that inhabit these ecosystems.

Pesticide seed treatments are regulated by EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), which directs the agency to evaluate whether the use of any pesticide proposed for registration presents "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and *benefits*."

"Their impact on honey bees, other pollinators and on the nation's beekeepers is especially troubling. Because the available scientific studies show little if any benefit, EPA should suspend all neonicotinoid seed treatment product registrations as required under FIFRA until the costs and benefits are adequately reviewed," said Jenkins.

"Although there is no doubt that neonicotinoids are highly toxic to insects, this does not mean they are routinely effective in pest management. In many contexts they provide no benefit, and in others they are not a cost-effective option. The bottom line is these toxic insecticides are being unnecessarily applied to seeds in most cases, while harming pollinators and the environment," said Sarah Stevens, researcher and co-author of the report.

"The economic costs of neonicotinoid seed treatments are real. In addition to paying for unnecessary treatments, the overuse of these pesticides has led to significant costs to society at large," added Stevens.

Dr. Christian Krupke of Purdue University, a top bee scientist and reviewer of the report, will be speaking at a briefing on Capitol Hill on Wednesday, 3/20/14, to discuss his own research on this topic. He will be joined by UK expert Dr. David Goulson of the University of Sussex, whose background research is relied on in the report. Dr. Goulson is an outspoken bee expert who made major contributions to the EU decision to suspend many neonicotinoid uses for a

minimum of two years. Interviews with them about the topics in the CFS report and their statements to Congress and regulators can be arranged through Center for Food Safety.

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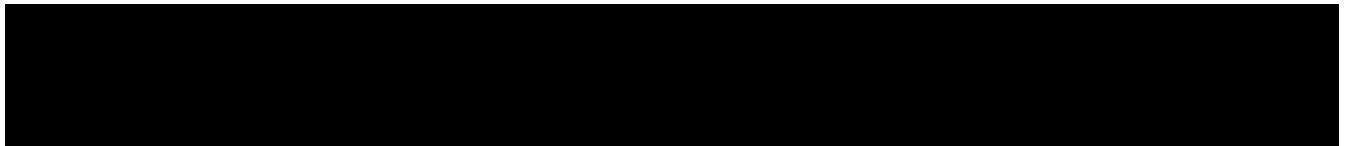
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From: [Epstein, David](#)
To: [Guilaran, Yu-Ting](#)
Cc: [Kunickis, Sheryl](#)
Subject: USEPA Neonic Sd Trt Benefits Assessment
Date: Wednesday, October 15, 2014 8:36:29 AM

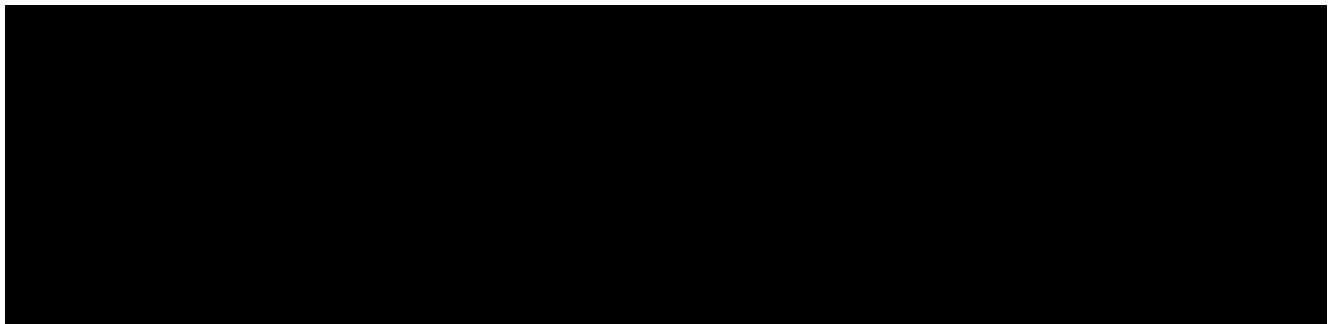
Yu Ting,

My comments in response to the USEPA document are below:

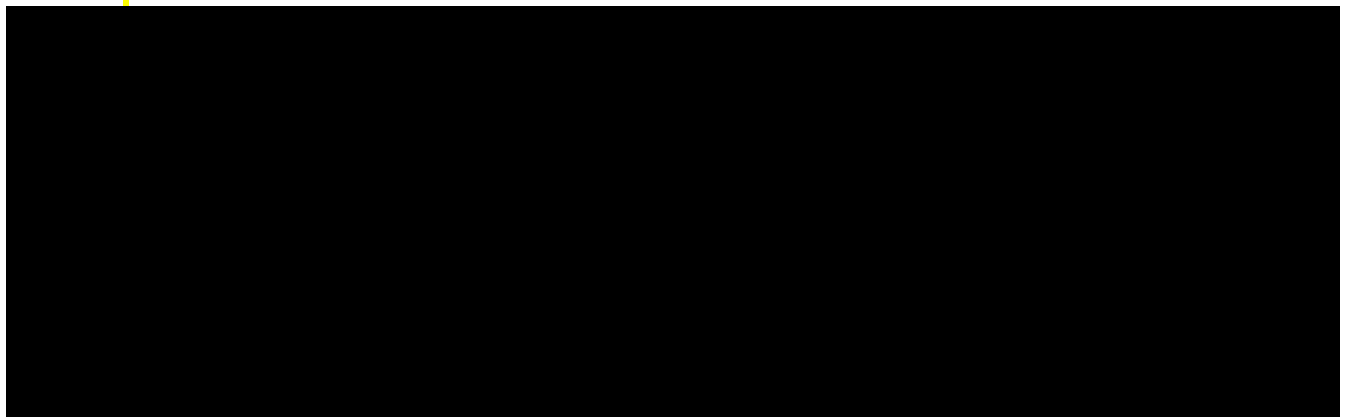
- "BEAD concludes that these seed treatments provide negligible overall benefits to soybean production in most situations. Published data indicate that in most cases there is no difference in soybean yield when soybean seed was treated with neonicotinoids versus not receiving any insect control treatment."



- "These alternatives to neonicotinoid seed treatments include foliar sprays of organophosphates (acephate, chlorpyrifos), synthetic pyrethroids (bifenthrin, cyfluthrin, gamma-cyhalothrin, lambda-cyhalothrin, deltamethrin, esfenvalerate, zeta-cypermethrin, permethrin), neonicotinoids (imidacloprid, thiamethoxam, clothianidin), and the recently registered sulfoxaflor, which works in a similar way to neonicotinoids."



- "Furthermore, neonicotinoid seed treatments as currently applied are only bioactive in soybean foliage for a period within the first 3-4 weeks of planting,..."



Regards,
David

David Epstein, Ph.D.
Senior Entomologist, USDA Office of Pest Management Policy
1400 Independence Ave SW
Room 3871 - South Bldg., Mail Stop 0314
Washington, DC 20250-0314
Office: (202) 720-9877
Work Mobile: (202) 603-9142
Personal Mobile: [REDACTED]
email: david.epstein@ars.usda.gov

From: [Keigwin, Richard](#)
To: [Kunickis, Sheryl - ARS](#)
Subject: FW: Neonics Meta-Analysis
Date: Wednesday, April 01, 2015 5:16:51 PM
Attachments: [Letter to Richard Keigwin re ARS Comments.docx.pdf](#)
[Comment to EPA re soybean neonics - AMB version.pdf](#)

FYI

This is what we received as the official submission. Note that the attachment continues to be marked draft.

From: Gibson, Loureatha - OSEC [mailto:Loureatha.Gibson@osec.usda.gov]
Sent: Wednesday, April 01, 2015 4:02 PM
To: Keigwin, Richard
Cc: Bartuska, Ann - OSEC
Subject: Neonics Meta-Analysis

Attached is an official transmittal letter from Ann Bartuska.

Thank you.

From: [Keigwin, Richard](#)
To: [Kunickis, Sheryl - OSEC](#)
Subject: RE: Soybean benefits
Date: Thursday, April 02, 2015 7:54:25 AM

You can send them to me. Email is fine. We'll get them added to the docket. No worries. Thanks!

-----Original Message-----

From: Kunickis, Sheryl - OSEC [<mailto:Sheryl.Kunickis@osec.usda.gov>]
Sent: Thursday, April 02, 2015 7:10 AM
To: Keigwin, Richard
Subject: Soybean benefits

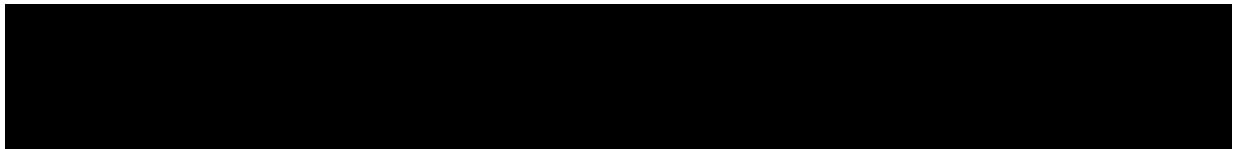
I may have been able to get you (EPA) the USDA comments on benefits..soybeans..seed treatment. Should they be directed to you and may I send them via email and hard copy as the docket is closed? That is assuming I am successful!

From: [Guillaran, Yu-Ting](#)
To: [Epstein, David](#)
Cc: [Kunickis, Sheryl](#); [Kiely, Timothy](#); [Jones, Arnet](#)
Subject: RE: USEPA Neonics Sd Trt Benefits Assessment
Date: Wednesday, October 15, 2014 4:16:09 PM

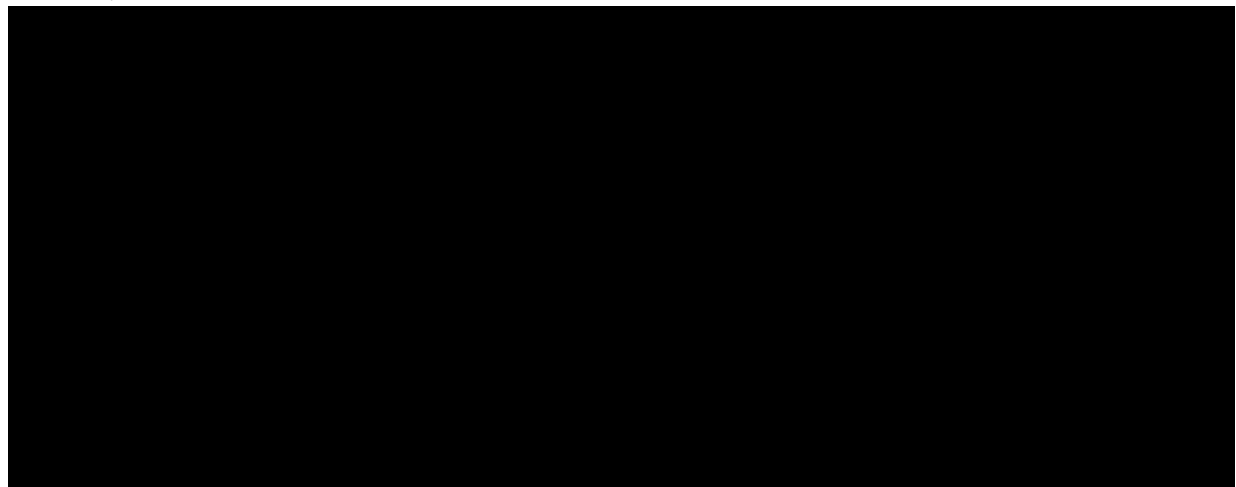
Hi David and Sheryl

Thank you for your comments. Here are our responses, please let me know if you have any questions or additional thoughts. Thanks again!

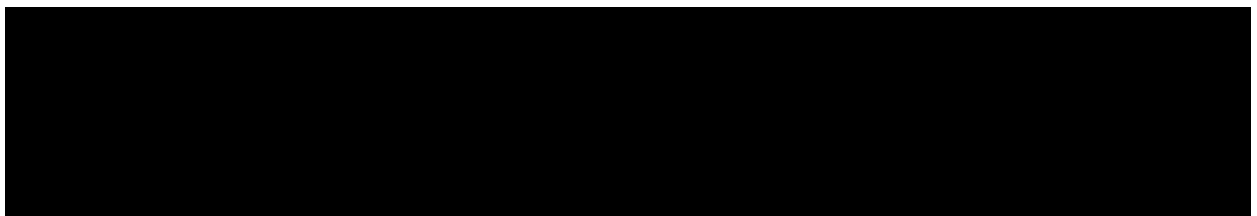
- "BEAD concludes that these seed treatments provide negligible overall benefits to soybean production in most situations. Published data indicate that in most cases there is no difference in soybean yield when soybean seed was treated with neonicotinoids versus not receiving any insect control treatment."



Response:



- "These alternatives to neonicotinoid seed treatments include foliar sprays of organophosphates (acephate, chlorpyrifos), synthetic pyrethroids (bifenthrin, cyfluthrin, gamma-cyhalothrin, lambda-cyhalothrin, deltamethrin, esfenvalerate, zeta-cypermethrin, permethrin), neonicotinoids (imidacloprid, thiamethoxam, clothianidin), and the recently registered sulfoxaflor, which works in a similar way to neonicotinoids."



Inter-agency deliberative communication

[REDACTED]

Response:

[REDACTED]

- "Furthermore, neonicotinoid seed treatments as currently applied are only bioactive in soybean foliage for a period within the first 3-4 weeks of planting..."

[REDACTED]

Response:

[REDACTED]

Response:

[REDACTED]

Regards,

Yu-Ting Guilaran, P.E.
Director

Biological and Economic Analysis Division (BEAD)
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
(tel) 703 308 0052
(fax) 703 308 8091
Mail code 7503P
Room number PY S9723

From: [Kunickis, Sheryl - OSEC](#)
To: [Johansson, Robert - OCE](#); [Abbott, Linda - OCE](#)
Subject: FW: Neonics meta-analysis
Date: Tuesday, January 27, 2015 11:25:51 AM
Attachments: [Comment to EPA re soybean neonics - AMB version.pdf](#)

Rob and Linda,

Please see attached. ARS submitted comments separate from USDA on the neonic seed treatment and soybean issue. Have either of you ever received a copy of the letter and supporting comments that went from OSEC? I sent Melinda a request for the final, but she never responded. Rob - you may be able to get it under your new Acting position.

Thanks,
Sheryl

-----Original Message-----

From: Bartuska, Ann - OSEC
Sent: Tuesday, January 27, 2015 11:03 AM
To: Keigwin, Richard; Hackett, Kevin; Jones, Jim
Cc: Cep, Melinda -OSEC; Kunickis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting
Subject: RE: Neonics meta-analysis

All, Attached are comments from ARS/USDA. Thanks for giving us time to provide these.

Regards, Ann

Ann M. Bartuska, PhD
Deputy Under Secretary for Research,
Education and Economics
USDA
202-720-1542

-----Original Message-----

From: Keigwin, Richard [<mailto:Keigwin.Richard@epa.gov>]
Sent: Monday, January 26, 2015 6:58 PM
To: Hackett, Kevin; Jones, Jim; Bartuska, Ann - OSEC
Cc: Cep, Melinda -OSEC; Kunickis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting
Subject: Re: Neonics meta-analysis

Kevin--

I wanted to follow-up on your earlier note. Does USDA have any feedback on the analysis we issued for public comment?

--Rick

Rick Keigwin
Director, Pesticide Re-evaluation Division Office of Pesticide Programs US Environmental Protection Agency

From: Hackett, Kevin <Kevin.Hackett@ARS.USDA.GOV>
Sent: Friday, December 12, 2014 7:55 AM

To: Jones, Jim; Bartuska, Ann - OSEC
Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kunickis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting
Subject: RE: Neonics meta-analysis

Jim, We can submit some comments within 30 days. If you are interested in the analysis we are just embarking on, we can provide that in a year, if that would also be of use. Kevin

Kevin J. Hackett, Ph.D.
Senior National Program Leader
USDA/Agricultural Research Service
5601 Sunnyside Ave, 4-2222
Beltsville, MD 20705-5139
301-504-4680 (office)
301-504-6191 (fax)
Kevin.Hackett@ars.usda.gov

-----Original Message-----

From: Jones, Jim [<mailto:Jones.Jim@epa.gov>]
Sent: Friday, December 12, 2014 7:40 AM
To: Bartuska, Ann - OSEC
Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kunickis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting; Hackett, Kevin
Subject: Re: Neonics meta-analysis

Ann, we won't be formally extending the comment period. That being said we will give full consideration to the analysis USDA is working on. It would be much appreciated if it could be submitted within 30 days. Thx

Jim Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Original Message
From: Bartuska, Ann - OSEC
Sent: Thursday, December 11, 2014 1:11 PM
To: Jones, Jim
Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kunickis, Sheryl - OSEC; Collantes, Margarita; Brady, Donald; Housenger, Jack; Guilaran, Yu-Ting; Hackett, Kevin
Subject: Re: Neonics meta-analysis

Jim, our folks could get a response together with a 30 day extension; the more though meta-analysis will take a year as it will include plumbing unpublished results. Ann

Dr. Ann M. Bartuska
Deputy Under Secretary for
Research, Education and Economics
USDA
202-720-1542

> On Dec 10, 2014, at 11:57 AM, "Jones, Jim" <Jones.Jim@epa.gov> wrote:
>
> Ann, I think a conference call on the meta analysis would be great. Rick can organize the key players in the Pesticides Program.
>
> On the second issue can you let me know when your data is expected to

> be submitted to us on soybean seed efficacy? Thx

>

> -----Original Message-----

> From: Bartuska, Ann - OSEC [<mailto:Ann.Bartuska@osec.usda.gov>]

> Sent: Wednesday, December 10, 2014 10:36 AM

> To: Jones, Jim

> Cc: Cep, Melinda -OSEC; Keigwin, Richard; Kunickis, Sheryl - OSEC

> Subject: Neonics meta-analysis

>

> Jim, If you recall, this was the last point of discussion we had with you last week. As it turns out, I got a message from Kevin Hackett shortly after, that a team of ARS scientists are doing this exact thing as part of their revised 5 year research plan. Even better, David Epstein, OPMP has a bunch of data that they gathered and is going to work with Tom Sappington (ARS, Ames).

>

> I wanted you to be aware of this activity; happy to set up a conference call with your staff to discuss.

>

> I understand the public comment period on the recent neonicotinoids analysis closes Dec 22. Because it would be of use to EPA's risk assessment, I am requesting EPA to extend its public comment period on their recent analysis of neonic efficacy and soybeans. The ARS analyses could significantly contribute to your findings and it seems to be advantageous to demonstrate interagency collaboration. In a perfect world, an extension of a year would give the scientists time to fully analyze studies and data, but any extension would be helpful.

>

> Thank you for your consideration of this request. Ann

>

> Dr. Ann M. Bartuska

> Deputy Under Secretary for

> Research, Education and Economics

> USDA

> 202-720-1542

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 15 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Benefits of Neonicotinoid Seed Treatments to Soybean Production

FROM: Clayton Myers, Ph.D., Entomologist
Biological Analysis Branch

Elizabeth Hill, Economist
Economic Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Arnet Jones, Chief
Biological Analysis Branch

Timothy Kiely, Chief
Economic Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Neil Anderson, Chief
Risk Management and Implementation Branch I
Pesticide Re-evaluation Division (7508P)

Peer Review Date: October 3, 2014

SUMMARY

The Biological and Economic Analysis Division (BEAD) analyzed the use of the nitroguanidine neonicotinoid seed treatments for insect control in United States soybean production. Imidacloprid, thiamethoxam, and clothianidin are applied to seeds at mostly downstream seed treating facilities prior to distribution to growers prior to planting. BEAD concludes that these seed treatments provide negligible overall benefits to soybean production in most situations. Published data indicate that in most cases there is no difference in soybean yield when soybean seed was treated with neonicotinoids versus not receiving any insect control treatment. Furthermore, neonicotinoid seed treatments as currently applied are only bioactive in soybean foliage for a period within the first 3-4 weeks of planting, which does not overlap with typical periods of activity for some target pests of concern. This information, along with current usage

data, suggests that much of the existing usage on soybeans is prophylactic in nature. Multiple foliar insecticides are available in instances where pest pressure necessitates a pest management tactic and such foliar insecticides have been found to be as efficacious as neonicotinoid seed treatments for target pests. These alternatives to neonicotinoid seed treatments include foliar sprays of organophosphates (acephate, chlorpyrifos), synthetic pyrethroids (bifenthrin, cyfluthrin, gamma-cyhalothrin, lambda-cyhalothrin, deltamethrin, esfenvalerate, zeta-cypermethrin, permethrin), neonicotinoids (imidacloprid, thiamethoxam, clothianidin), and the recently registered sulfoxaflor, which works in a similar way to neonicotinoids. In most cases, these alternatives are comparable in cost to one another and to neonicotinoid seed treatments. The cost of application was considered in this comparison, although because these alternatives can be tank-mixed with other chemicals that are typically applied to soybeans, additional passes over a field would not be necessary. In comparison to the next best alternative pest control measures, neonicotinoid seed treatments likely provide \$0 in benefits to growers and at most \$6 per acre in benefits (i.e., a 0%-1.7% difference in net operating revenue). Some neonicotinoid seed treatment usage could provide an insurance benefit against sporadic and unpredictable pests, particularly in the southern United States. However, BEAD did not find information to support the real-world significance of this benefit, and overall evidence indicates that any such potential benefit is not likely to be large or widespread in the United States.

BACKGROUND

This document analyzes how nitroguanidine neonicotinoid seed treatments (imidacloprid and thiamethoxam) are currently used in soybeans (e.g., target pests), alternatives to seed treatments, and the biological and economic benefits of imidacloprid and thiamethoxam seed treatments compared to other pest control options. Clothianidin is also registered for seed treatment use on soybeans, but its usage is minor in comparison to imidacloprid and thiamethoxam, and its relevance will be discussed later. Imidacloprid and thiamethoxam are registered for use as seed treatments on soybeans to control both foliar and soil dwelling pests, particularly soybean aphids, bean leaf beetles, wireworms, seed maggots, cutworms, and other minor pests. These treatments are most often applied to seeds at designated seed treatment facilities in combination with other active ingredients or additives, including fungicides, nematicides, fertilizers, growth enhancers, and/or accompanying stickers, adjuvants, and lubricants. Some growers can buy custom blends of treated seeds based upon their pest management needs, and most do not typically treat their own seeds at planting. Imidacloprid is applied to seeds at a rate of up to 62.5 g active ingredient (AI)/100 lbs of seed, while thiamethoxam is typically applied at 50-100 g AI/100 lbs of seed. While imidacloprid, thiamethoxam, and clothianidin are also registered for post-emergent foliar application to soybeans, this analysis is focused only on the benefits of imidacloprid and thiamethoxam seed treatments. Since foliar sprays of neonicotinoids (and other insecticides) can target the same pest spectrum as neonicotinoid seed treatments, they are considered as potential alternatives in this analysis.

SOYBEAN PRODUCTION AND UTILIZATION IN THE UNITED STATES

In the United States, the Corn Belt, the Great Lakes, and the Northern Plains Regions are the major production areas for soybeans. The primary states include Illinois, Iowa, Minnesota, and North Dakota. Table 1 summarizes U.S. soybean production and values in recent years. From 2009-2013, an average of 76 million acres of soybean were harvested annually; this is up from previous years, with average acres harvested from 2004-2008 at 71 million acres annually. The average price per bushel has almost doubled, from \$7.65/bu from 2004-2008 to \$12.03 from 2009-2013. Although there was only a 7% increase in average annual production from 2004-2008 to 2009-2013, a recent 9% increase in total production from 2012 to 2013 may be an indicator of future increases in soybean production, which is likely in response to recent increases in export demand for soybeans (USDA NASS, 2010-2014; Wilson, 2014).

Table 1: Soybeans: Average Annual Production and Value (2009-2013)

	PRICE RECEIVED (\$/BU)	TOTAL ACRES HARVESTED (1000 ACRES)	YIELD (BU/ACRE)	GROSS REVENUE / ACRE	TOTAL PRODUCTION (1000 BU)	VALUE of PRODUCTION (\$1000)
Corn Belt¹	\$12.24	33,636	46.23	\$566	1,554,947	\$18,908,122
Great Lakes²	\$11.87	10,610	42.19	\$501	447,618	\$5,322,595
Northeast³	\$12.06	1,508	38.69	\$466	64,474	\$782,909
Northern Plains⁴	\$11.86	17,282	38.69	\$459	668,692	\$7,860,885
Southeast⁵	\$12.01	12,724	51.03	\$613	485,095	\$5,859,460
United States	\$12.03	75,760	44.60	\$538	3,220,826	\$38,733,969

Source: Crop Product Summary and Crop Values Summary (USDA NASS, 2010-2014). Numbers may not add due to rounding.

1 Illinois, Indiana, Iowa, Missouri, and Ohio

2 Michigan, Minnesota, and Wisconsin

3 Delaware, Maryland, New Jersey, New York, and Pennsylvania

4 Kansas, Nebraska, North Dakota, and South Dakota

5 Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia

USE OF NEONICOTINOID SEED TREATMENTS ON SOYBEANS

On average, from 2008-2012, neonicotinoid-treated seeds were applied on 30% of soybean acres, (with some individual years approaching 40% of soybean acres). This ratio is roughly the same for every region in the United States, with the exception of the Northeast, where only 16% of acres were planted with neonicotinoid-treated seeds. By comparison, approximately 46% of soybean acres were reported to receive a seed treatment of some type as of 2009, which also included treatment with other insecticides, fungicides, nematicides, etc. Most of these seed treatments (39% of U.S. soybean acreage) were applied at downstream seed treating facilities, compared to 5% applied at commercial seed treating facilities and 2% applied by the grower prior to planting (Proprietary Seed Treatment Survey Data, 2009).

The primary neonicotinoid seed treatments for soybeans are imidacloprid and thiamethoxam. While clothianidin is also registered for use on soybeans as a seed treatment, it is used on less than 1 million acres on average from 2008-2012 (EPA Proprietary Data, 2014), which is low in comparison to imidacloprid and thiamethoxam. Furthermore, since the bioactivity and efficacy against target pests of clothianidin is functionally equivalent to thiamethoxam on soybeans, the conclusions from this memo would also apply to clothianidin seed treatments. Overall, slightly more acres of soybeans receiving neonicotinoid seed treatments in the United States were with thiamethoxam relative to imidacloprid; however this varies by region (Table 2). The highest use in terms of acres treated and pounds applied for both imidacloprid- and thiamethoxam-treated seeds was in the Corn Belt, followed by the Northern Plains.

Table 2: Soybean Acreage and Neonicotinoid Seed Treatment Usage Data, 2008-2012

	Corn Belt¹	Great Lakes²	Northeast³	Northern Plains⁴	Southeast⁵	Total
Acres Grown	33,900,000	10,782,000	1,505,800	17,210,000	13,165,600	76,563,400
Percent Acres Treated						
Imidacloprid	16%	11%	9%	10%	7%	12%
Thiamethoxam	16%	20%	7%	22%	22%	19%
Total ⁶	32%	31%	16%	32%	28%	31%
Acres Treated						
Imidacloprid	5,413,000	1,141,000	133,000	1,663,000	908,000	9,258,000
Thiamethoxam	5,368,000	2,142,000	109,000	3,818,000	2,830,000	14,267,000
Total ⁶	10,781,000	3,283,000	242,000	5,481,000	3,738,000	23,526,000
Pounds Applied						
Imidacloprid	433,600	92,000	12,400	123,700	74,100	735,700
Thiamethoxam	151,700	63,800	3,300	110,800	85,600	415,200
Total ⁶	585,300	155,800	15,700	234,400	159,700	1,151,000

Source: Crop Product Summary and Crop Values Summary (USDA NASS, 2010-2014); EPA Proprietary Data.

Numbers are rounded and reflect 5-year averages.

1 Illinois, Indiana, Iowa, Missouri, and Ohio

2 Michigan, Minnesota, and Wisconsin

3 Delaware, Maryland, New Jersey, New York, and Pennsylvania

4 Kansas, Nebraska, North Dakota, and South Dakota

5 Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia

6 Totals do not include the small amount of acreage treated with clothianidin (less than 1 million acres annually)

KEY EARLY-SEASON INSECT PESTS OF SOYBEANS

EPA proprietary usage data, derived from grower pesticide usage surveys (2004-2012) indicate that when insect pests are explicitly targeted by seed treatments, the national leading target pests are soybean aphid and bean leaf beetle. These pests were targets for seed treatments on approximately 20% of soybean acreage nationally from 2004-2012. Most growers (approximately 65%) did not indicate any specific target insect pests driving their usage of

soybean neonicotinoid seed treatment products, suggesting that a large majority of usage in soybean could actually be prophylactic in nature, rather than in response to a specifically identified problem.

Of the pests identified as being targets for neonicotinoid seed treatments, soybean aphid is a particular pest of concern given its recent arrival to the U.S. Soybean aphid (*Aphis glycines* Matsumura) is an invasive pest that was first discovered in the mid-western U.S. in 2000 (Krupke et al., 2010). It is a piercing/sucking insect pest that feeds on soybean foliage and causes stress to the plant that can adversely affect yield at high aphid densities. The bean leaf beetle (*Cerotoma trifurcata*) is a chewing feeder on soybean foliage. Other identified pests, measured as the percentage of U.S. crop acreage treated, include wireworm (10%), seed maggots (9%), and cutworms (4%). Because multiple target pests can be listed in the surveys that comprise the usage data, these percentages are not additive. In southeastern states in the U.S., the three-cornered alfalfa hopper was also listed by survey respondents as a significant early season target pest for seed treatments on soybeans. This pest does not typically occur in problematic numbers in regions outside the Southern U.S. (NC State, 2014) and is most often a problem in reduced-tillage systems and areas near unmanaged field margins due to the pest overwintering in plant debris (Stewart et al. 2014).

Because of the limited early season bioactivity of seed treatments (3-4 weeks from planting) (MSU, 2014; NDSU, 2014; Purdue, 2014; PSU, 2014), only early-season occurring pests are considered in this analysis. These pests include soybean aphids, bean leaf beetles, cutworms, thrips, three-cornered alfalfa hoppers (which mostly only occur in the Southern U.S.), and the soil pest complex, which includes wireworms and seed maggots. Management of other pests that occur later in the season—or those that fall outside the activity spectrum of imidacloprid and thiamethoxam, such as other Lepidopteran pests of soybeans—are not considered in this analysis and may have a different spectrum of alternative treatments and/or require different management approaches than the pests listed above.

CHEMICAL CONTROL OF KEY EARLY-SEASON INSECT PESTS OF SOYBEANS

Historically, insecticide use on soybeans has been infrequent. EPA's source of proprietary usage information (2014) did not survey insecticide usage on soybeans prior to 2004. Historical data from USDA showed that total U.S. insecticide usage on soybeans averaged less than 430,000 lbs active ingredient (AI) per year between 1987-2004 (Fernandez-Cornejo et al., 2014), compared with an average of 3.9 million lbs AI (3.0 million lbs AI if seed treatments are excluded) per year from 2008-2012 (EPA Proprietary Data, 2014). In general, soybeans are known to be well adapted to foliage stress, compensating for foliage loss from insects and other damage sources without significant loss of bean yield. Foliage loss thresholds range from 15-35% depending on the time of the season (PSU, 2014). Prior to the arrival of the invasive soybean aphid, historically lower soybean prices probably resulted in few instances where insecticide usage on soybeans would have been economically justifiable.

Neonicotinoid seed treatments were first registered for use on soybeans in 2004 and grower adoption has increased appreciably since the uses were first captured in 2006 usage surveys

(EPA Proprietary Data, 2014). Numerous effective alternatives (foliar sprays) are also registered for the same foliar pests of soybeans that are targeted by neonicotinoid seed treatments. Table 3 summarizes the published extension recommendations from research universities representing the Corn Belt, the Northern Plains, the Southeast, and the Northeast for control of soybean aphids, bean leaf beetles, cutworms, and three cornered alfalfa hoppers. Recommended foliar alternatives include organophosphates (acephate, chlorpyrifos), synthetic pyrethroids (bifenthrin, cyfluthrin, gamma-cyhalothrin, lambda-cyhalothrin, deltamethrin, esfenvalerate, permethrin, zeta-cypermethrin), neonicotinoids (imidacloprid, thiamethoxam, clothianidin), and the recently registered sulfoxaflor, which is classified as neonicotinoid-like. It is notable that none of the cited extension sources recommended neonicotinoid seed treatments for control of soybean aphid. Additional questionnaire data from soybean extension experts (NCIPMC, 2014), which will be discussed later in more detail, indicate that in most instances, seed treatments are ineffective against soybean aphids, as these aphids are not typically present/active in soybean fields during the early season period of neonicotinoid bioactivity in newly emerged soybeans. While soybean aphids can occur during the early season, most infestations, especially those above treatment thresholds, occur later in the growing season. However, seed treatments are only effective at killing soybean aphids when aphids are active in soybean fields during this 3-4 week period of bioactivity. Therefore, insecticidal seed treatments on soybeans are not often effective at managing most soybean aphid infestations on a season-long basis. Since aphid populations are often low in the early season, it is difficult to predict how such an early season impact may affect subsequent population growth. For the states that do recommend seed treatments for bean leaf beetle (PSU, 2014) and three cornered alfalfa hopper control (MSU, 2014), the recommendations again are clearly qualified to indicate that control should only be expected for the first 3-4 weeks after planting.

Table 3: University Extension Recommendations for Insecticide Tools Targeting 4 Important Foliar Pests of Soybeans Based on Efficacy

Important Foliar Pests of Soybeans Based on Efficiency								
	Soybean Aphid		Bean Leaf Beetle		Cutworms		Three- Cornered Alfalfa Hopper	
Insecticide	Extension Recommended Materials? (Yes = Y) with Sources of Recommendations							
Acephate	Y	2, 3	Y	1, 2, 3			Y	1
Chlorpyrifos	Y	2, 3, 4	Y	2, 3, 4	Y	3, 4		
Cyfluthrin	Y	2, 3, 4	Y	1, 2, 3, 4	Y	1, 3, 4	Y	1
Bifenthrin	Y	2, 3, 4	Y	1, 2, 3, 4	Y	1, 3, 4		
Deltamethrin	Y	2, 3, 4	Y	2, 3, 4	Y	3, 4		
γ-cyhalothrin	Y	2, 3, 4	Y	1, 2, 3, 4	Y	1, 3, 4	Y	1
λ-cyhalothrin	Y	2, 3, 4	Y	1, 2, 3, 4	Y	1, 3, 4	Y	1
Esfenvalerate	Y	2, 3, 4	Y	1, 2, 3, 4	Y	1, 3, 4	Y	1
Z-cypermethrin	Y	2, 4	Y	1, 2, 4	Y	1, 4	Y	1
Permethrin			Y	1, 2, 3, 4	Y	1, 3, 4		
Imidacloprid (foliar)	Y	3	Y	3				
Clothianidin (foliar)	Y	3	Y	3	Y	4		
Sulfoxaflor (foliar)	Y	3						
Imidacloprid (seed trt.)			Y*	2			Y#	1
Thiamethoxam (seed trt.)			Y*	2			Y#	1

Sources:

1-Mississippi State University, 2014

2-Penn State University, 2014

3-North Dakota State University, 2014

4-Purdue University, 2014

*Indicates that control is for early season only

#Indicates that control is only seen for the first 3-4 weeks after planting

Product Performance Against Foliar Pests of Soybeans:

Beyond the published extension efficacy recommendations listed above, BEAD evaluated available product performance data for the neonicotinoid seed treatments and alternative foliar sprays against the most important soybean pests. There were relatively few instances where significant yield protection was demonstrated for neonicotinoid seed treatments in comparison to an untreated control (i.e., applying no insecticides). For soybean aphid and bean leaf beetle in particular, only 5 out of 60 published comparisons showed any significant yield protection from either thiamethoxam or imidacloprid seed treatments when compared to doing nothing (Hammond, 2006; Jewett and DiFonzo, 2007a; Magalhaes et al., 2009; McCornack and Ragsdale, 2006a; Whitworth, 2005).

BEAD reviewed 34 published comparisons for thiamethoxam and 26 comparisons for imidacloprid from a total of 26 published efficacy studies in online university extension publications and the Entomological Society of America's online journal of Arthropod

Management Tests (Davis et al., 2010; Echtenkamp and Hunt, 2005, 2006a-b, 2007; Estes et al., 2004a-b, 2005a-b, 2006, 2007; Hammond, 2002, 2003, 2005, 2006; Heeren et al., 2008; Hodgson and VanNostrand, 2011; Jewett and DiFonzo, 2007a-c; McCornack and Ragsdale, 2006b; Tinsley et al., 2007, 2011; Way et al., 2005 Whitworth, 2005, 2006). BEAD also reviewed 9 peer-reviewed articles that evaluated the field efficacy of neonicotinoid seed treatments in some way (Cox et al., 2008; Cox and Cherney, 2011; Johnson et al., 2009; Magalhaes et al., 2009; McCornack and Ragsdale, 2006b; Ohnesorg et al., 2009; Reisig et al., 2012; Seagraves and Lundgren, 2012; Tinsley et al., 2013). In studies that included a comparison to foliar insecticides, there were no instances where neonicotinoid seed treatments out-performed any foliar insecticide in yield protection from any pest. In the majority of cases, yield was not significantly different between plots treated with neonicotinoid seed treatments at planting versus those treated with foliar sprays. In the few instances where significant differences were reported, it was the foliar spray treatments that resulted in higher yields than soybeans with seed treatments.

Other Regional/Sporadic Pest Considerations:

Soil insects, such as wireworms and seed maggots, are also listed as target pests for some of the surveyed usage of neonicotinoid seed treatments (EPA Proprietary Data, 2014). One efficacy study demonstrated that an imidacloprid seed treatment protected soybean yield in a field with a high infestation of seed corn maggot. The observed efficacy was comparable to seed treatments of permethrin, diazinon, and lindane (Hammond, 2002). However, other similar studies in the same region failed to show significant yield effects for either imidacloprid or thiamethoxam when compared to untreated controls (Hammond, 2003, 2005). BEAD found no studies that explicitly evaluated efficacy against wireworms in soybeans, though efficacy against wireworm in other crops such as corn, cotton, and vegetables is well-established. Historically, usage of soil insecticides has been negligible on U.S. soybeans (EPA Proprietary Data, 2014). Furthermore, usage of alternative chemical seed treatments, including permethrin, which is a commonly recommended alternative for seed maggot control (Purdue 2014, NDSU 2014), is also negligible overall, with use never exceeding 0.5% of U.S. soybean acreage from 2004-2012 (EPA Proprietary Data, 2014). This indicates that soil pests such as seed maggot and wireworms have not historically driven pesticide usage in soybeans.

Another pest consideration that is unique to soybean growers in the Southern U.S. is the three cornered alfalfa hopper. Extension publications indicate that this pest is sporadic in nature and is often a higher risk in low-tillage systems and late planted (or later season double-crop) soybeans (MSU, 2014; Stewart et al. 2014). However, extension sources do recommend usage of seed treatments against this pest when planting into a known area of pest pressure (MSU, 2014). Hopper feeding causes girdling damage to young soybean plants and the thresholds for treatment are based upon the number or percentage of plants damaged by this feeding. One study from Louisiana compared a number of seed treatments for yield protection from three-cornered alfalfa hopper and showed that an experimental thiamethoxam seed treatment (similar in AI dosing to the commercial products) did significantly protect yield. However, yields from eight other formulations of thiamethoxam and imidacloprid in the same study were no different than an untreated control (Davis et al, 2010). Another efficacy study from Texas also showed no

difference in yield between neonicotinoid seed treatments and an untreated control (Way et al., 2005). Much like the situation discussed above with soil insects, historical insecticide usage targeting this pest is very low, averaging less than 1% of national soybean acreage from 2004-2012 (EPA Proprietary Data, 2014). Given the known ability of soybeans to compensate for reductions in plant/foliage density and the sporadic occurrence of this pest, it difficult to project how much, if any, yield protection is gained by seed treatments targeting three-cornered alfalfa hopper.

Additional Unpublished Data:

In the summer of 2014, the North Central IPM Center (NCIPMC) collected information through a questionnaire and additional unpublished data on neonicotinoid seed treatment efficacy, target pests, and benefits from national research and extension experts on a number of crops. The stated purpose of the questionnaire was to “gather input from researchers who have been working on neonicotinoid seed treatment projects and whose results/data have not yet been published.” Overall, researchers completed a total of 37 questionnaires. For the soybean portion of this questionnaire effort, 21 respondents representing 17 states (IA, IN, KS, LA, MD, MI, MN, MS, NC, ND, NE, OH, PA, SD, TN, TX, and VA) submitted responses.

Some key findings of the questionnaire were related to the perceived yield benefits of neonicotinoid seed treatments and the impact on the number of foliar insecticide sprays made to soybeans. When asked how the use of neonicotinoid-treated seeds affected soybean yields, 74% of respondents (14/19) responded that yield either stayed the same or decreased. All of the 5 respondents who indicated that seed treatments increased soybean yield were researchers working in the Southern U.S., specifically LA, MS, and TN (NCIPMC, 2014). When asked if the use of seed treatments affected the amount of foliar pesticide applications on soybeans, 100% of the respondents indicated that foliar sprays (both aerial and ground) either stayed the same or actually increased (NCIPMC, 2014).

With regard to specific pest efficacy, there was almost universal agreement that neonicotinoid seed treatments are not typically effective against soybean aphids. This is because the limited period of bioactivity in soybeans (i.e., first 3-4 weeks) does not usually align with periods of soybean aphid presence/activity. Similarly, neonicotinoid seed treatments are not effective in controlling bean leaf beetles as this pest occurs too late in the season (NCIPMC, 2014). In both cases, adequate alternatives are available to control these pests via foliar applications. And in both cases, foliar applications of insecticides are more amenable to treating pest outbreaks on a threshold basis. When asked when (i.e., under what conditions) growers should use neonicotinoid seed treatments, 11 of 20 respondents (55%) indicated that they should only be used under specific conditions—for example, when planting soybeans into a known area of high infestation, when double-cropping soybeans after wheat, or when planting early in the season. Ten percent of respondents (2 of 20) indicated that seed treatments should always be used on soybeans (both respondents were from the Southern U.S.) to protect yield from unpredictable early season pest issues. One third of respondents (7 of 21) indicated that neonicotinoid seed treatments should never be used on soybeans because they are too costly and do not deliver a significant pest management benefit. One of the respondents who indicated that seed treatments

should only be used under specific conditions cited evidence from a manuscript submitted for peer review, and shared with BEAD, that indicates seed treatments used in the Northeastern U.S. may actually decrease soybean yields by increasing the populations of soybean-damaging slugs. Interestingly, it appears this happens due to a tri-trophic disruption of predator populations that would otherwise control slugs (Douglas, et al., unpublished data).

ECONOMIC BENEFITS OF NEONICOTINOID SEED TREATMENTS

There are no clear or consistent economic benefits of neonicotinoid seed treatments in soybeans. The next best alternative to neonicotinoid seed treatment is foliar spraying of various organophosphate, pyrethroid, and neonicotinoid insecticides. Nearly all soybean growers are already making foliar pesticide applications of some sort and thus have access to the necessary equipment for application. In addition, growers would not have to make an additional field pass as foliar alternative insecticides that target the same pest spectrum as neonicotinoid seed treatments are applied at the same time as a number of current foliar sprays (including herbicides, fungicides, miticides, etc.) and can be tank mixed. No yield gains are expected from neonicotinoid seed treatments, which means the only potential economic impact would be the cost of an insecticide used as a foliar spray. In the case of soybeans, thiamethoxam and imidacloprid seed treatments cost approximately \$7 and \$8 an acre, respectively, with an average cost of \$7.50 (weighted by acres treated) (EPA Proprietary Data, 2014). Of the 11 viable foliar insecticides identified in this study that could potentially be used for the control of foliar soybean pests (including co-formulated mixes of multiple AI's), all cost less than \$7/A, with the exception of flubendiamide which, on average, costs around \$14/A. This also includes foliar sprays of the neonicotinoid insecticides thiamethoxam, clothianidin, and imidacloprid. In making a conservative estimate (i.e., assuming the highest possible grower benefits from using neonicotinoid seed treatments), BEAD considers the cost per acre of flubendiamide, the most expensive alternative. Given this upper-bound alternative cost assumption, growers are still not expected to see more than a 1.7% increase in net operating revenue using neonicotinoid seed treatments in lieu of a foliar spray (Table 4). This upper bound scenario is unlikely however, given the historically low use of flubendiamide on soybeans. More likely, soybean growers in need of a foliar alternative to neonicotinoid treated seeds will select equivalently priced, commonly used alternatives, thus incurring no economic impact. It is also possible that growers may experience a loss in net revenue when applying prophylactic seed treatments if there are no pests present to be targeted, as they would not have derived any benefit from the treatment.

Table 4: Upper Bound Estimate of the Average Economic Benefits to Soybean Growers in the U.S. from Using Neonicotinoid Seed Treatments.

	Neonicotinoid Seed Treatments Scenario	Flubendiamide Foliar Treatment Scenario
Yield (bu/A)	45	45
Price (\$/bu)	\$12.03	\$12.03
Gross Revenue (\$/A)	\$536	\$536
Insecticide Costs (\$/A)		
seed treatment	\$8	
foliar spray		\$14
Other Variable Costs (\$/A) ¹	\$173	\$173
Total Variable Operating Costs (\$/A)	\$180	\$186
Net Operating Revenue	\$356	\$350
Percent Change in Net Operating Revenue	+1.70%	

Source: Crop Product Summary and Crop Values Summary (USDA NASS, 2010-2014); USDA ERS Commodity Costs and Returns (2013); EPA Proprietary Data, 2014. Numbers may not add due to rounding.

1. Includes the cost of other insecticides, chemical applications, and seeds. Has been adjusted to account for the cost/A of neonicotinoid seed treatments.

Since no significant yield gains are expected for soybeans from the use of neonicotinoid seed treatments, any national benefits will be reflected in net operating revenue through changes in production costs. When considering the upper bound estimate, growers may derive a value from neonicotinoid treated seed of approximately \$6/acre if switching to the most costly foliar treatment. EPA proprietary data show that on average from 2004 to 2012, approximately 65% of soybean growers in the U.S. indicated that they had no pest they were targeting when using neonicotinoid-treated seed. With 30% of the 75 million acres of soybeans in the U.S. being treated with neonicotinoid seed treatments, this implies that approximately 8.6 million of the 23 million soybean acres using neonicotinoid seed treatments derive potential benefits from the application. Multiplying through, if 8.6 million acres of soybeans derive benefits from neonicotinoid-treated seeds, the total benefit to soybean growers in the U.S. from neonicotinoid-treated seed is at most \$52 million, or 0.14% of the total value of soybean production in the U.S., with the total value of soybeans being \$38.7 billion/year, on average, from 2009-2013. Again, these benefits are unlikely given the very low historical usage of the most costly foliar alternative and the equivalent cost of comparable alternatives for the pests targeted by neonicotinoid treated soybean seeds.

GROWER CHOICE IN SEED TREATMENT USAGE

One issue of note is the availability of untreated seed relative to treated seed. While proprietary survey data indicates that the vast majority of soybean seed receiving seed treatment is treated at a downstream seed treating facility (EPA Proprietary Data, 2009), data from researchers and extension experts (NCIPMC, 2014) indicate that some growers currently have some difficulty obtaining untreated seed. Of the 20 responses from NCIPMC's soybean seed treatment expert questionnaire on the question of seed availability, 45% indicated that soybean seed not treated with neonicotinoids is either "difficult to obtain" (8 of 20 respondents) or "not available" (1 of

20 respondents). The other 55% (11 of 20 respondents) indicated that untreated seed was “easy to obtain.” One respondent indicated that even with downstream-treated seeds, growers sometimes have problems de-coupling insecticide options from other seed treatment products such as fungicides. For example, a grower purchasing seed treated with a particular fungicide may have no choice but to purchase neonicotinoid insecticide treatments on the same lot of seeds (NCIPMC, 2014).

UNCERTAINTIES IN THE ANALYSIS:

With regard to three-cornered alfalfa hoppers and soil insects such as wireworms and seed maggots, which are commonly found in high numbers in the Southern U.S., our analysis indicated that these pests have not historically driven pesticide usage. However, it is possible that soybean growers have achieved some yield protection or ‘insurance’ benefit by usage of neonicotinoid seed treatments. Indeed, extension publications do recommend the use of a seed treatment (either neonicotinoids or permethrin) when planting soybeans into a known area of high seed maggot infestation or prior damage. Similarly for three-cornered alfalfa hoppers, Mississippi State University (2014) lists seed treatments as an effective tactic for protecting soybeans for 3-4 weeks after planting.

Given the sporadic nature of these pests, it is difficult to project how much actual yield protection is gained on a year to year basis from the use of seed treatments, especially without knowing the potential for injury prior to planting. It is of note that all of NCIPMC’s informational responses (5 of 19, 26%) that indicated seed treatments led to an increase in soybean yield (NCIPMC, 2014) were from researchers working in the Southern U.S. (LA, MS, and TN). These respondents indicated that three-cornered alfalfa hoppers, thrips, and the soil pest complex were the main drivers behind the benefits of seed treatments. When asked how the loss of neonicotinoid seed treatments would affect production in their states, three of the five respondents indicated that major yield losses were not likely to occur on a widespread basis. Three of the five respondents also indicated that soybeans would be more at risk from early season pests. One respondent estimated that regional yield losses would be less than three bushels per acre, while one other respondent estimated that profitability would be decreased in most situations. When asked when (i.e., under what circumstances) growers should use neonicotinoid seed treatments, two responded “always” and three responded “only under specific circumstances” which included “cool, high stress” or “wet” conditions and early planting conditions where pest pressure is expected to be high, such as on land that was previously used for pasture or left fallow (NCIPMC, 2014).

Earlier in this memo, BEAD discussed data indicating that the yield impact of thrips is not significant for the Southern U.S. (Reisig et al., 2012). While seed treatments could potentially provide some insurance benefit for losses by seed maggots or alfalfa hoppers in cases where early season pressure is high, it is unknown how common or widespread this situation might be. Further, in many instances, the potential severity of pest pressure, especially for soil pests, can be difficult to predict. Given the availability of effective alternatives and the historically negligible usage of permethrin seed treatments, soil insecticides, or other foliar insecticides targeting these pests, BEAD at this time sees no evidence to indicate that associated yield loss risks on soybeans

would be large or widespread in the absence of neonicotinoid seed treatments. Furthermore, depending on the effectiveness of scouting and efficacy of other threshold-based pest management tactics, the relative benefit of such preventative control may be reduced if/when growers are aware of pest activity soon after planting and have time to apply an insecticide. However, given cropping practices, pest pressure considerations and the difficulty of scouting for pest pressure prior to planting, it appears at least plausible that insurance benefits of seed treatment usage could be higher for the Southern U.S. growing region relative to the rest of the country. Conversely, it is also possible that even though historical usage of soil insecticides is reported to be low, future shifts to soil insecticide applications could potentially offer a similar insurance benefit to that observed by usage of neonicotinoid seed treatments

The following additional information, with supporting evidence, would be helpful to EPA in addressing existing or heretofore unknown uncertainties regarding benefits of neonicotinoid seed treatments on soybeans:

1. Whether significant 'insurance' benefits exist in the southern United States or elsewhere for prophylactic neonicotinoid seed treatment, including specific information on the yield impacts of sporadic pests and the corresponding impacts of preventative seed treatments on soybean yield.
2. The positive or negative consequences of neonicotinoid seed treatment usage within the broader soybean IPM context.
3. The impacts of seed treatment to pesticide resistance management in soybeans.
4. Additional cost savings or expenditures for soybean production that were not adequately captured by BEAD's benefit analysis.

CONCLUSION

This analysis provides evidence that U.S. soybean growers derive limited to no benefit from neonicotinoid seed treatments in most instances. Published data indicate that most usage of neonicotinoid seed treatments does not protect soybean yield any better than doing no pest control. Given that much of the reported seed treatment usage in the U.S. on soybeans is not associated with a target pest, BEAD concludes that much of the observed use is preventative and may not be currently providing any actual pest management benefits. In cases where pest pressure does necessitate some type of insect control, efficacious alternatives are available for the key foliar pests of soybeans at a comparable cost per acre. These alternatives include foliar sprays of the same neonicotinoid active ingredients that are currently being used as seed treatments. These alternatives are sometimes already used in combination with (i.e., subsequent to) neonicotinoid seed treatments, as seed treatments ultimately have a very short early-season period of bioactivity.

At most, the benefits to soybean growers from using neonicotinoid treated seeds are estimated to be 1.7% of net operating revenue in comparison to soybean growers using foliar insecticide

treatments. This estimate is very conservative because it is based on the assumption that growers currently using neonicotinoid seed treatments will choose to use the most expensive foliar alternative, which has historically low usage against the pests targeted by neonicotinoid seed treatments. It is more likely, based on the available data that growers will choose to make no application or use foliar alternatives that are equivalently priced to neonicotinoid seed treatments.

In instances where seed treatments may provide some insurance benefit against unpredictable outbreaks of sporadic pests, such as seed maggots or three cornered alfalfa hoppers, BEAD cannot quantify benefits with currently available information. However, this insurance benefit may exist for some growers, particularly those in the Southern U.S. Given currently available information, BEAD projects that any such benefits are not likely to be large or widespread, given the negligible historical pesticide usage targeting these pests in soybeans.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Benefits of Neonicotinoid Seed Treatments to Soybean Production

FROM: Clayton Myers, Ph.D., Entomologist
Biological Analysis Branch

Elizabeth Hill, Economist
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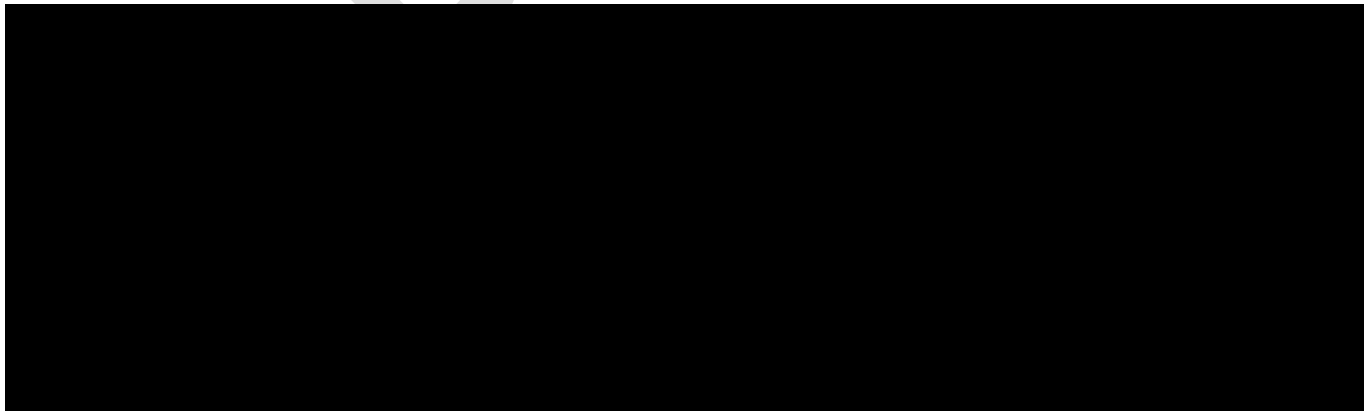
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Timothy Kiely, Chief
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TO: Neil Anderson, Chief
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Pesticide Re-evaluation Division (7508P)

Peer Review Date: October 3, 2014

SUMMARY



**Sulfur Registration Review
Summary Document:
Initial Docket
March 2008**

Case #0031

Approved By:


 3/19/08
Steve Bradbury, Ph.D.
Director, Special Review and
Reregistration Division

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I. PRELIMINARY WORK PLAN

Introduction:

The Food Quality Protection Act of 1996 mandated a new program: registration review. All pesticides distributed or sold in the United States generally must be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency has begun to implement the new registration review program, and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of sulfur.

Elemental sulfur is a naturally occurring component of the earth's core and crust and is ubiquitous in the environment. Sulfur has been used as a pesticide in the United States since the 1920s, and is currently registered for use as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops, livestock (and livestock quarters), and indoor and outdoor residential sites. Use sites include tree fruit, berries, vegetables, root crops, field crops, pets (dogs), ornamentals, and turf (including residential lawns and golf courses). Sulfur is also one of the active ingredients in four fumigant (gas-producing) cartridge products which are used for rodent control on lawns, golf courses, and in gardens.

Anticipated Risk Assessment and Data Needs:

Ecological Risk:

The Agency anticipates conducting a comprehensive ecological risk assessment, including an endangered species assessment, for all outdoor and gas-cartridge uses of sulfur. No additional data are required at this time.

- In 1991, the EPA issued a Reregistration Eligibility document (RED) for sulfur. The Agency concluded that since sulfur is a ubiquitous element in the

environment and an essential nutrient for some organisms, it appears to pose little risk to non-target species.

- Available acute toxicity studies support this conclusion, indicating that sulfur is practically nontoxic on an acute basis to birds, mammals, insects, freshwater fish, and freshwater and estuarine/marine invertebrates.
- All other ecological effects data are waived at this time. EPA will complete an open literature search using the ECOTOX database to look for toxic effects in non-target taxa. If additional data exist, an evaluation will be made as to whether or not the data are adequate for use in a risk assessment.
- All environmental fate data requirements for sulfur also have been waived because sulfur is a naturally occurring element whose behavior in the environment is well-understood and described in published literature.
- The Agency plans to conduct a new ecological risk assessment for the outdoor and gas-cartridge uses of sulfur to support a complete endangered species determination. The planned assessment will allow the Agency to determine whether sulfur use has “no effect” or “may affect” federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that sulfur “may affect” a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether the use of sulfur is “likely to adversely affect” the species or critical habitat or “not likely to adversely affect” the species or critical habitat. When an assessment concludes that a pesticide’s use “may affect” a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

Human Health Risk:

The Agency anticipates conducting new occupational and residential exposure assessments for all uses of sulfur. Based on reported incidents, a subchronic inhalation study is required to assess risk to handlers.

- The most recent and comprehensive human health risk assessment for sulfur was conducted in 1990 to support the 1991 RED. Based on the natural occurrence of sulfur in food and in the environment, EPA determined that sulfur is generally recognized as safe for use as a pesticide and is exempted from tolerances. As a result, no dietary, residential, or aggregate risk assessment was conducted. No new dietary or aggregate risk assessment is needed at this time.
- The EPA Inert Ingredient Focus Group assessed sulfur as a member of the “weathered materials” inert ingredients in 2002. EPA re-evaluated and reaffirmed the tolerance exemption for sulfur at that time.

- In response to California incident data, a qualitative occupational risk assessment was conducted which recommended that a 24-hour re-entry interval be established for foliar applications, and that workers wear personal protective equipment such as coveralls, chemical-resistant gloves, and goggles during mixing, loading and application.
- Acute toxicity is low. Acute oral toxicity is category IV, while acute dermal and inhalation are category III. Sulfur is an eye and skin irritant (Category III), but it is not a skin sensitizer. No subchronic or chronic toxicity studies are available.
- However, due to the large number of reported incidents associated with the use of sulfur, in particular incidents related to respiratory problems, a subchronic inhalation study is required to assess risk to handlers.
- During registration review, EPA will further examine reported incidents for sulfur and will revise the human health incident report prior to issuing a DCI. If the revised report indicates that current PPE requirements are adequate to protect handlers, or if the Agency receives information during the comment period to indicate that a subchronic inhalation study is unnecessary, a DCI will not be issued.
- EPA will conduct a quantitative occupational and residential exposure assessment.

Timeline:

EPA has created the following estimated timeline for the completion of the sulfur registration review.

Registration Review of Sulfur: Projected Registration Review Timeline	
Activities	Estimated Year/Month
Phase 1: Opening the docket	
Open Public Comment Period for Sulfur	2008 — March
Close Public Comment Period	2008 — June
Phase 2: Case Development	
Final Work Plan (FWP)	2008 — July–Sept.
Issue DCI	2009 — April–June
Data Submission	2011 — April–June
Preliminary Risk Assessment and Public Comment	2012 — Oct.–Dec.
Close Public Comment Period	2013 — Jan.–March
Phase 3: Registration Review Decision	
Proposed Registration Review Decision	2013 — April–June
Public Comment Period	2013 — July–Sept.

Final Registration Review Decision and Begin Post-Decision Follow-up	2013 — Oct.–Dec.
Total (years)	5

Guidance for Commenters:

The public is invited to comment on EPA’s preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided prior to issuing a final work plan for the sulfur case.

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. There are no U.S. tolerances for sulfur, nor are there Codex MRLs, so trade irritants are not expected for sulfur.

Sulfur is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://oaspub.epa.gov/tmdl/waters_list impairments?p_impid=3. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the “OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP’s Registration Review Risk Assessment and Management Process” (see: <http://www.epa.gov/oppfead1/cb/ppdc/2006/november06/session1-sop.pdf>), in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to sulfur used as a pesticide, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical or unusually high exposure compared to the general population.

Stakeholders are also specifically asked to provide information and data that will assist the Agency in refining the human health and ecological risk assessments, including any species-specific effects determinations. The Agency is interested in the following information:

1. Confirmation on the following label information.
 - a. sites of application
 - b. formulations
 - c. application methods and equipment

- d. maximum application rates in units related to mass per unit area of treatment zone
 - e. frequency of application, application intervals, and maximum number of applications per season
 - f. geographic limitations on use.
- 2. Use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant uses).
- 3. Use history.
- 4. Median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state, and county.
- 5. Application timing (date of first application and application intervals) by use – national, state, and county.
- 6. Sub-county crop location data.
- 7. Usage/use information for non-agricultural uses (*e.g.*, golf courses, athletic fields, ornamentals).
- 8. Directly acquired county-level usage data (not derived from state level data).
 - a. maximum reported use rate (lbs. a.i./acre) from usage data – county
 - b. percent crop treated – county
 - c. median and 90th percentile number of applications – county
 - d. total pounds per year – county
 - e. the year the pesticide was last used in the county/sub-county area
 - f. the years in which the pesticide was applied in the county/sub-county area
- 9. Typical application interval (days).
- 10. State or local use restrictions.
- 11. Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.

Next Steps:

After the comment period closes, the Agency will review the comments received, and then issue a Final Work Plan for this pesticide.

II. FACT SHEET

Background Information:

- Sulfur Registration Review Case Number: 0031
- Sulfur PC Code: 077501
- Sulfur CAS#: 7704-34-9
- Technical Registrants (company number): Wilbur Ellis Co. (2935), Georgia Gulf Sulfur Corp. (6325), Gowan Co. (10163), Drexel Chemical Co. (19713), Quimetal Industrial S.A. (62562), Biesterfeld U.S., Inc. (62575), Arysta Lifescience North America Corp. (66330), Integro, Inc. (79702), and Martin Operating Partnership, LP (82571).
- First U.S. registration in the 1920s.
- No U.S. tolerances.
- Special Review and Reregistration Division (SRRD), Chemical Review Manager (CRM): Véronique C. LaCapra (lacapra.veronique@epa.gov)
- Registration Division (RD) contacts: Tamue Gibson (gibson.tamue@epa.gov) and Mary Waller (waller.mary@epa.gov)

Use & Usage Information:

For additional details, please refer to the BEAD *Appendix A* document in the sulfur docket.

- Sulfur is an insecticide and fungicide.
- Based on the natural occurrence of sulfur in food and in the environment, EPA determined that sulfur is exempt from tolerances.
- Sulfur is currently registered for use under FIFRA Section 3 as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops, livestock (and livestock quarters), and indoor and outdoor residential sites. Use sites include tree fruit, berries, vegetables, root crops, field crops, pets (dogs), ornamentals, and turf (including residential lawns and golf courses). Sulfur is also one of the active ingredients in four fumigant (gas-producing) cartridge products which are used for rodent control on lawns, golf courses, and in gardens.
- Sulfur is formulated as a dust, wettable powder, water dispersible granules (dry flowable), emulsifiable concentrate, flowable concentrate, liquid, liquid ready-to-use, and gas cartridge.
- Sulfur can be applied via aircraft, groundboom, ground dust rig, sprinkler irrigation, soil incorporation, pneumatic applicator, handheld sprayer, backpack sprayer, hand-held duster, spoon, and by hand.

Recent Actions:

- The most recent and comprehensive ecological and human health risk assessments for sulfur were completed in support of the 1991 Reregistration Eligibility Decision (RED). Since the RED was completed, there have been no new regulatory actions for sulfur (other than “me-too” registrations).

Ecological Risk Assessment Status:

Please refer to Section III, Ecological Risk Assessment Problem Formulation, for a detailed discussion of the anticipated ecological risk assessment needs. The following ecological outcomes and anticipated data needs are based on the limited data and risk assessments currently available:

- Since sulfur is a naturally-occurring element that is ubiquitous in the environment, it appears to pose little risk to non-target species. Available acute toxicity studies support this conclusion. All other ecological toxicity data requirements are waived, and no new data are required at this time.
- All environmental fate data requirements for sulfur have been waived because sulfur is a naturally occurring element whose behavior in the environment is well-understood and described in published literature.
- The Agency plans to conduct new ecological risk assessments for the outdoor and gas-cartridge uses of sulfur to support a complete endangered species determination.
- The Agency is interested in obtaining specific use information and other data outlined in Section III of this document.

Human Health Risk Assessment Status:

Please refer to Section IV of this document, Human Health Effects Scoping Document, for a detailed discussion of the anticipated risk assessment needs for human health. The following is a summary of those anticipated needs:

- The acute toxicity of sulfur is low: sulfur is classified as category IV for acute oral toxicity and category III for acute dermal and inhalation toxicity. Sulfur is an eye and skin irritant (category III), but it is not a skin sensitizer. No subchronic or chronic toxicity studies are available.

Dietary (Food and Water):

- Sulfur is a naturally-occurring element in food and the environment, and is insoluble in water. Consequently, sulfur is exempt from tolerances and no dietary risks are anticipated from exposure to sulfur in food or drinking water.
- The EPA Inert Ingredient Focus Group assessed sulfur as a member of the “weathered materials” inert ingredients in 2002. EPA also reassessed the tolerance exemption for sulfur.
- No new dietary (food or drinking water) assessment is needed at this time.

Residential:

- EPA did not conduct a residential risk assessment for the 1991 RED. Due to the large number of reported incidents for sulfur, EPA will conduct a residential risk assessment in Registration Review.

Occupational:

- In response to reported incidents in California, EPA conducted a qualitative occupational risk assessment for sulfur. Resulting mitigation included a 24-hour re-entry interval for foliar applications and the requirement that handlers wear

personal protective equipment such as coveralls, chemical-resistant gloves, and goggles during mixing, loading and application.

- Based on the large number of reported incidents, including many involving respiratory symptoms, EPA is requiring a subchronic inhalation study and will conduct a quantitative occupational risk assessment.
- Prior to issuing a DCI, EPA will complete a refined incident report. If the revised report indicates that current PPE requirements are adequate to protect handlers, or if the Agency receives information during the comment period to indicate that a subchronic inhalation study is unnecessary, a DCI will not be issued.

Incidents:

Ecological incidents:

- The Ecological Incident Information System (EIIS) lists three incidents associated with the use of sulfur, all resulting in damage to terrestrial plants. In one incident, there was reported damage to 127 acres of citrus treated directly with sulfur. The certainty index for this incident was “probable”. A second incident report indicated damage to 44 acres of a grape vineyard treated directly with sulfur and trifloxystrobin. The symptoms noted were spotting and speckling. The certainty index for this incident was “possible” for sulfur and “probable” for trifloxystrobin. In the third reported incident a tank mixture of sulfur, fenarimol, and oxyfluorfen applied to 20-acre plot of grapes may have caused burnt leaves and berries. The certainty index for this incident was “unlikely” for sulfur and fenarimol, and “probable” for oxyfluorfen.
- No ecological incidents have been reported associated with the use of the rodent control, gas-producing cartridge products of sulfur.

Human health incidents:

- EPA has conducted a preliminary review of incident data for sulfur used as a pesticide.
- Sulfur was the active ingredient responsible for the largest numbers of acute occupational pesticide-related illnesses in the 1998-1999 Sensor data (78 cases). Most were cases involving farm workers performing routine work activities other than pesticide application. A preliminary review of other available data indicates that there are incidents associated with the application of sulfur pesticide products, as well.
- EPA will conduct a complete review of human incident data for sulfur prior to issuing a final Registration Review work plan.

Data Call-In Status:

No Data Call-In has been issued for sulfur.

Tolerances:

Currently no U.S. tolerances or Mexican, Canadian, or CODEX MRLs exist for sulfur.

Labels:

Nine technical registrations, one-hundred and fourteen end-products, and three Special Local Need registrations are currently active for sulfur. A full list of these products is available in the docket. Labels can be obtained from the Pesticide Product Label System (PPLS) website: <http://oaspub.epa.gov/pestlabl/ppls.home>. Technical registration numbers are listed, below:

Sulfur Technical Registrations			
Registration Number	Product name	Company Name	Active Ingredient
2935-480	Wilbur-Ellis Technical Sulfur	Wilbur Ellis Co.	Sulfur
6325-14	Yellow Jacket Sulfur Flowers	Georgia Gulf Sulfur Corp.	Sulfur
10163-141	Sulfur Base	Gowan Co.	Sulfur
19713-315	Drexel Sulfur Technical	Drexel Chemical Co.	Sulfur
62562-5	Sulphur Technical	Quimetal Industrial S.A.	Sulfur
62575-10	Global Technical Suffa	Biesterfeld U.S., Inc.	Sulfur
66330-229	Superfine Flour Sulfur	Arysta Lifescience N.A. Corp.	Sulfur
79702-2	Integro Sulfur Tech	Integro, Inc.	Sulfur
82571-2	CSC Technical Sulfur	Martin Operating Partnership, LP	Sulfur

III. ECOLOGICAL RISK ASSESSMENT PROBLEM FORMULATION

This section includes two problem formulation documents, the first of which begins on p. 13, and the second on p. 37.

The first addresses the majority of sulfur outdoor pesticidal uses. Sulfur is registered for use as an insecticide and fungicide on a wide range of field-grown food and feed crops, livestock (and livestock quarters), and outdoor residential sites. Use sites include tree fruit, berries, vegetables, root crops, field crops, ornamentals, and turf (including residential lawns and golf courses). The ecological problem formulation document that addresses these uses of sulfur is entitled, “*Problem Formulation for Ecological Risk Assessment for Sulfur.*”

Sulfur is also one of the active ingredients in four fumigant (gas-producing) cartridge products which are used for rodent control on lawns, golf courses, and in gardens. These products also include the active ingredients carbon and inorganic (potassium or sodium) nitrate. The ecological problem formulation document that addresses these uses of sulfur is entitled, “*Problem Formulation for Ecological Risk Assessment, for Carbon Dioxide and Gas Fumigant Producing Cartridges: Carbon, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur.*”



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PC Code 077501
Case No. 0031
DP Barcode 346696

MEMORANDUM

DATE: February 7, 2008

SUBJECT: Problem Formulation for Ecological Risk Assessment for Sulfur

FROM: José Luis Meléndez, Chemist *José Luis Meléndez*
Jean Holmes, DVM, Risk Assessment Process Leader *Jean Holmes*
Environmental Risk Branch V
Environmental Fate and Effects Division (7507P)

THROUGH: Mah T. Shamim, Ph.D., Chief *Mah T. Shamim*
Environmental Risk Branch V
Environmental Fate and Effects Division (7507P)

TO: Veronique LaCapra, Chemical Review Manager
Margaret Rice, Chief
Reregistration Branch II
Special Review and Reregistration Division

Please find attached the ecological risk assessment problem formulation for all sulfur uses except for the gas cartridge use. The sulfur gas cartridge use was addressed in the "Problem Formulation for Ecological Risk Assessment for Carbon Dioxide and Gas Fumigant Producing Cartridges: Carbon, Sawdust, Sodium Nitrate, potassium Nitrate and Sulfur".

**Problem Formulation,
For Ecological Risk Assessment,
For Sulfur**

List A
Case Number #0031

Environmental Fate and Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency



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Problem Formulation

The purpose of this problem formulation is to provide the foundation for the ecological risk assessment that will be conducted for sulfur. It includes all sulfur uses except for the gas cartridge use. As such, it articulates the purpose and objectives of the risk assessment, evaluates the nature of the problem, and provides a plan for analyzing the data and characterizing the risk (EPA, 1998).

A. Nature of Regulatory Action

This report summarizes the Environmental Fate and Effects Division's Problem Formulation for the Registration Review of Sulfur. This chemical belongs to List A Case Number 0031. In 1991, the USEPA issued a Reregistration Eligibility document for Sulfur, which serves as the basis for this assessment (USEPA, 1991). At the time, it was concluded that since sulfur is a ubiquitous element in the environment and an essential nutrient for some organisms, it appears to pose a small hazard to non-target organisms. This was supported by data that showed low order toxicity to various species tested.

B. Stressor Source and Distribution

1. Nature of the Chemical Stressor

Sulfur accounts for 15% of the inner core of the earth and 0.052% of its crust. It occurs both in free state and in combination, mainly as sulfides and sulfates (HSDB). Sulfur (CAS No. 7704-34-9; PC Code 077501) is a fungicide and insecticide with an atomic mass of 32.06 g/mol. It is insoluble in water. Table II.1 provides some basic characteristics of sulfur. The Fungicide Resistance Action Committee (FRAC) has designated sulfur as FRAC Code M2 (the only chemical in the group); the chemical belongs to the broader mode of action (MOA) of multi-site contact activity, belonging to the target site and code inorganic. Sulfur disrupts electron transport along the cytochromes. Its resistance risk is generally considered low.

Elemental Sulfur, when applied as a pesticide, will become incorporated into the natural sulfur cycle. The main processes and dissipation of elemental sulfur are oxidation into SO_4^{2-} and reduction into S^{2-} . These processes are mainly mediated by microbes.

Figure II.1. Sulfur Deposit

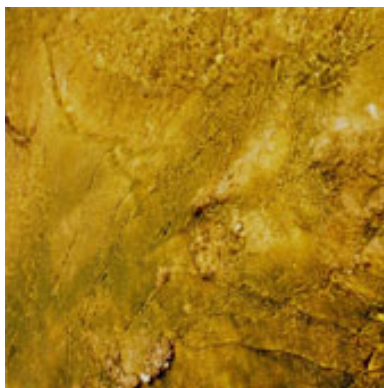


Table II.1. Nature of the Chemical Stressor	
Common name	<i>Sulfur</i>
Chemical name	<i>Sulfur</i>
Pesticide type	<i>Fungicide, Insecticide, Acaricide</i>
Chemical class	<i>NA</i>
CAS number	<i>7704-34-9</i>
Empirical formula	<i>S</i>
Atomic mass (g/mol)	<i>32.064</i>
Color/Form	<i>Precipitated sulfur is in form of very fine, pale yellow, amorphous or microcrystalline powder</i>
Odor/Taste	<i>Odorless/Tasteless or Faint Taste</i>
Melting Point	<i>112.8 to 120°C</i>
Boiling Point	<i>444.6 °C</i>
Vapor pressure	<i>3.95X10⁻⁶ mm Hg at 30.4°C</i>
Henry's Law Constant (atm-m ³ /mol)	<i>NA</i>
Solubility in water	<i>Insoluble in Water</i>
Solubilities	<i>1 g/2 ml carbon disulfide ~2.4% in benzene @ 30°C Sol in Toluene 2.65% dissolves in acetone @ 25°C 9.1% dissolves in methylene iodide @ 10°C ~1.5% dissolves in chloroform @ 18°C</i>
log K _{OW}	<i>N/A</i>
PK _a /PK _b	<i>N/A</i>
NA=Not Available; Source HSDB (web); N/A=Not Applicable.	

2. Overview of Pesticide Usage

Sulfur is considered both a fungicide and an insecticide. Sulfur may be used on numerous crops and there are numerous products containing sulfur as the active ingredient. According to the USGS map (see Fig. II.2 below), sulfur is used all throughout the continental United States, but primarily in the East and West, South, and Midwest regions. The map does not represent a specific year, but rather shows typical use patterns over the five year period 1999 through 2004, with emphasis on the 2002 Census of Agriculture.

The Screening Level Usage Analysis (SLUA) represents available estimates of pesticide usage for sulfur when used on agricultural crops in the US. It can be assumed that data are the average pounds of active ingredient applied (sulfur) obtained by merging a variety of data sources. Also, the SLUA provides the average percent of crop treated and the maximum percent of crop treated. The SLUA does not provide data on non-agricultural uses.

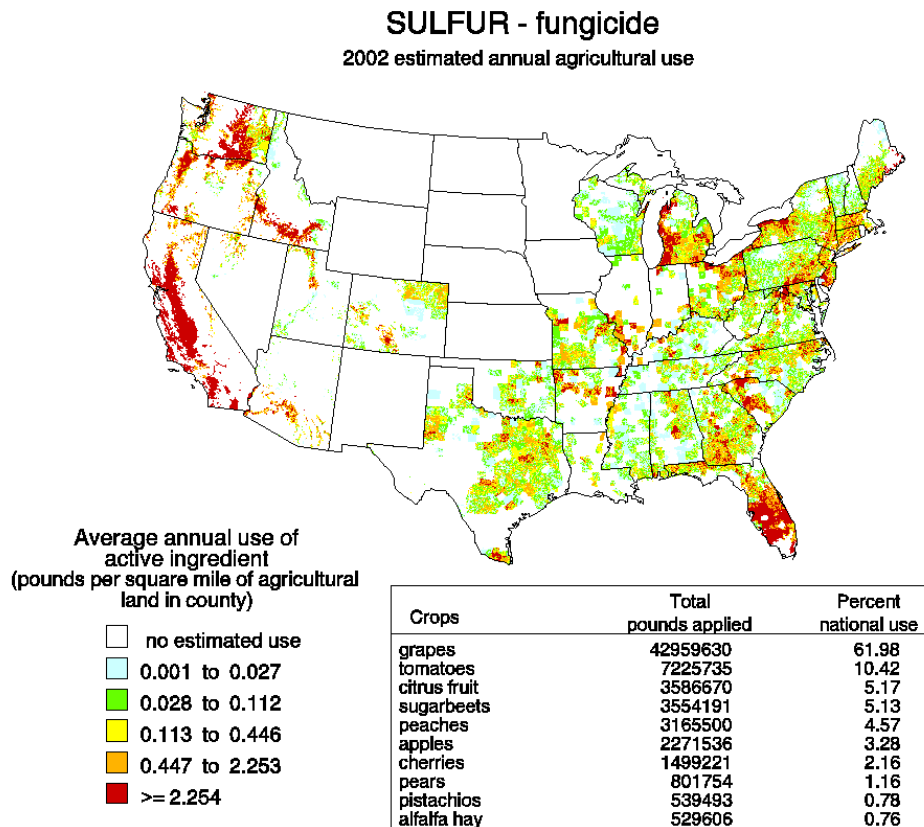


Fig. II.2. 2002 Pesticide Use Maps, Sulfur fungicide

Caution: The pesticide use maps available from the USGS site (http://ca.water.usgs.gov/pnsp/pesticide_use_maps/) show the average annual pesticide use intensity expressed as average weight (in pounds) of a pesticide applied to each square mile of agricultural land in a county. The area of each map is based on state-level estimates of pesticide use rates for individual crops that were compiled by the CropLife Foundation, Crop Protection Research Institute, based on information collected during 1999 through 2004 and on 2002 Census of Agriculture county crop acreage. The maps do not represent a specific year, but rather show typical use patterns over the five year period 1999 through 2004. Use intensity rates are expressed as the pounds applied per square mile of mapped agricultural land in a county. The area of mapped agricultural land for each county was obtained from an enhanced version of the 1992 USGS National Land Cover Data (NLCD). The key limitations of the data used to produce these maps include the following: (1) state use coefficients represent an average for the entire state and consequently do not reflect the local variability of pesticide management practices found within states and counties, (2) pesticide use estimates are not for a specific year, but represent typical use patterns for the five year period, (3) state pesticide use coefficients may not have been available for all states where a pesticide may have been applied to agricultural land, and therefore, are not displayed on the maps, (4) the county crop acreage is based on the 2002 Census of Agriculture and may not represent all crop acreage because of Census nondisclosure rules, and (5) agricultural land area used to calculate the pesticide use intensity and display the data was derived from 30-meter satellite remote sensing data that may over estimate or underestimate the actual agricultural land area. The maps are not intended for making local-scale estimates of pesticide use, such as estimates at the county level. Please refer to [Method for Estimating Pesticide Use](#) for a detailed discussion of how the pesticide use data were developed.

The SLUA, which is dated 12/05/2007, indicates that the crops of major use for sulfur are as summarized in Table II.2. It is noted that the first nine-ten crops in the SLUA and the USGS map are grapes, tomatoes, peaches, citrus, apples, cherries, sugar beets, pistachios and pears (approximately in the same order in both lists).

Table II.2. Sulfur Major Crops (at or exceeding 500,000 lb a.i. applied) According to SLUA dated 12/05/07.			
Crop	lb a.i. applied	% Crop Trtd Ave	% Crop Trtd Max
Grapes	45,200,000	80	90
Tomatoes	6,400,000	50	60
Peaches	2,800,000	60	70
Oranges	1,600,000	10	20
Apples	1,600,000	30	35
Cherries	1,200,000	50	50
Grapefruit	1,000,000	40	65
Sugar beets	800,000	5	5
Pistachios	600,000	35	45
Pears	600,000	50	65
Strawberries	500,000	45	60
Prunes	500,000	25	40
Carrots	500,000	25	55

On the other hand, usage data available for the state of California ¹ indicate that for the years 2003-2005, there was an increase in the total use of sulfur, as a pesticide, from 53,180,000 lb in 2003 to 61,230,000 lb in 2005. The major crops involved were tomatoes (processing), sugar beets, pistachios tomatoes and strawberries, approximately in that order.

Sulfur may be applied by chemigation, soil band treatment (ground sprayer, aircraft), soil treatment (soil incorporation treatment), low volume spray concentrate (low volume ground concentrate), high volume spray or dilute (high volume ground sprayer), or dust (ground or aircraft). Formulations include dust (D), water dispersible granules or dry flowable (DF), emulsifiable concentrate (EC), flowable concentrate (F1C), liquid (L), liquid ready-to-use (RTU), wettable powder (WP), and wettable powder/Dust (WP/P).

A sample label, Golden-Dew (Fungicide and Insecticide, Reg. No. 2935-407), provides some insight on how its registrant divided its use sites into various major categories:

Field Crops: such as alfalfa, cereals, clover, cotton, grass seed crops, hops, peanuts, soybeans, sugar beets, spearmint and peppermint

¹ California Department of Pesticide Regulations or CDPR, <http://www.cdpr.ca.gov/docs/pur/purmain.htm>, in a usage analysis prepared by BEAD on 11/28/07

Vegetable Crops: such as asparagus, beans and peas, carrots, garlic, peppers and onions, celery, broccoli, cauliflower and others, lettuce, melons and squash, turnips and others, potatoes, and tomatoes.

Fruits, Nuts and Berries: such as almond, apples, avocados, berries (various), citrus, figs, grapes, mangos, pears, pecans, pistachios, stone fruits (various), strawberries, walnuts and macadamias.

Ornamentals: such as laurels, chrysanthemums, juniper, spruce, English ivy, petunia, sage, cosmos, dogwood, hibiscus, holly, Lady's, lilac, sunflower and violets.

In this sample label, application rates for sulfur range from 3 to 30 lb a.i./A. Variation in application rate is probably related to crop and their tolerance to the chemical. However, there are a few other labels with application rates up to 122.5 lb a.i./A.

C. Receptors

1. Aquatic and Terrestrial Effects

The receptor is the biological entity that is exposed to the stressor (EPA, 1998.) Due to the outdoor uses of sulfur, the types of receptors that may be exposed to sulfur include both aquatic and terrestrial receptors, such as plants, birds, reptiles, mammals and freshwater and estuarine/ marine fish and non-target invertebrates. This list may not be comprehensive.

Consistent with the process described in the Overview Document (EPA, 2004), this risk assessment uses a surrogate species approach in its evaluation of sulfur. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) included under these taxonomic groupings.

There are seven acceptable studies on the ecological effects of sulfur. These studies indicate that sulfur is practically nontoxic on an acute basis. An eight day dietary study conducted on bobwhite quail resulted in an LC₅₀ value of > 5620 ppm. In that study, one mortality was reported at a test concentration of 1780 ppm. An acute oral rat toxicity study resulted in an LD₅₀ value of > 5g/kg with no mortalities reported. A study conducted on two fish species, rainbow trout and bluegill sunfish, resulted in an LC₅₀ value of >180 ppm. The study results of a 48 hour acute toxicity study conducted on daphnia and a 96 hour mysid shrimp study resulted in LC₅₀ values of >5,000 and 736 ppm respectively. Two beneficial insect studies demonstrated that sulfur is low in toxicity to the honey bee through contact and ingestion. All other ecological effects data are waived. No additional aquatic data are required due to the insoluble nature of sulfur and the low toxicity indicated in the available data. No chronic data are required based on, 1) the available acute toxicity data indicating that sulfur is practically nontoxic, and 2) the fact that sulfur in nature is ubiquitous and chronic exposure is common.

Available open literature will also be used to evaluate the potential direct effects of sulfur to the aquatic and terrestrial receptors identified in this section. This includes toxicity data on the technical grade active ingredient, and when available, formulated products.

At this time, a full and complete ECOTOX search has not been performed, but will be conducted prior to issuance of any Data Call-in. The open literature studies will be identified through EPA's ECOTOX database (<http://cfpub.epa.gov/ecotox/>), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife. The evaluation of data can also provide insight into the direct and indirect effects of sulfur on biotic communities from loss of species that are sensitive to the chemical and from changes in structure and functional characteristics of the affected communities.

Table II.3 provides a summary of the taxonomic groups and the surrogate species tested to help understand potential acute ecological effects of pesticides to these non-target taxonomic groups. In addition, the table provides a preliminary overview of the potential acute toxicity of sulfur by providing the acute toxicity classifications.

Table II.3. Test Species Evaluated for Assessing Potential Ecological Effects of Sulfur and the Associated Acute Toxicity Classification		
Taxonomic Group	Example(s) of Surrogate Species	Acute Toxicity Classification
Birds ¹	Mallard (<i>Anas platyrhynchos</i>) Bobwhite (<i>Colinus virginianus</i>)	Practically non-toxic
Mammals	Laboratory rat (<i>Rattus norvegicus</i>)	Practically non-toxic
Insects	Honey bee (<i>Apis mellifera</i> L.)	Practically non-toxic
Freshwater fish ²	Bluegill sunfish (<i>Lepomis macrochirus</i>) Rainbow trout (<i>Oncorhynchus mykiss</i>)	Practically non-toxic
Freshwater invertebrates	Water flea (<i>Daphnia magna</i>)	Practically non-toxic
Estuarine/marine fish	Sheepshead minnow (<i>Cyprinodon variegatus</i>)	Data waived
Estuarine/marine invertebrates	Mysid shrimp (<i>Americamysis bahia</i>) Eastern oyster (<i>Crassostrea virginica</i>)	Practically non-toxic
Terrestrial plants ³	Monocots – corn (<i>Zea mays</i>) Dicots – soybean (<i>Glycine max</i>)	Data waived
Aquatic plants and algae	Duckweed (<i>Lemna gibba</i>) Green algae (<i>Selenastrum capricornutum</i>)	Data waived

¹ Birds represent surrogates for terrestrial-phase amphibians and reptiles.

² Freshwater fish may be surrogates for aquatic-phase amphibians.

³ Four species of two families of monocots, of which one is corn; six species of at least four dicot families, of which one is soybeans.

Incident Reports

There were a total of three terrestrial plant incidents in the United States found in the Ecological Incident Information System (EIIS). In one incident, there was reported damage to 127 acres of citrus treated directly with sulfur. The symptoms were described as “miscellaneous”. It is unknown as to whether the application was made according to label guidelines. Also, no chemical analysis was conducted. The certainty index for this

incident was probable. The second incident report indicated damage to 44 acres of a grape vineyard treated directly with sulfur and trifloxystrobin. The symptoms noted were spotting and speckling. The application rate and method were not reported for sulfur but were reported for trifloxystrobin. The certainty index for this incident was possible for sulfur and probable for trifloxystrobin. Available terrestrial plant data for trifloxystrobin result in an EC₂₅ greater than the highest concentration tested; therefore an assessment of risks is not possible. However, another strobilurin fungicide is highly toxic to terrestrial plants. In the third reported incident a tank mixture of sulfur, fenarimol, and oxyfluorfen applied to 20-acre plot of grapes may have caused burnt leaves and berries. The certainty index for sulfur and fenarimol was unlikely and was probable for oxyfluorfen. The plant damage was more likely caused by the herbicide oxyfluorfen rather than to the fenarimol and sulfur fungicides. No incidents of contamination of surface, ground and drinking water have been reported to the Agency.

2. Ecosystems Potentially at Risk

The ecosystems at risk are often extensive in scope, and as a result it may not be possible to identify specific ecosystems during the development of a baseline risk assessment. However, in general terms, terrestrial ecosystems potentially at risk due to the use of sulfur, could include the treated field and areas immediately adjacent to the treated field that may receive drift or runoff. Areas adjacent to the treated field could include cultivated fields, fencerows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats and other uncultivated areas. As mentioned earlier, sulfur may be used on multiple crops.

Aquatic ecosystems potentially at risk due to the use of sulfur include water bodies adjacent to, or down stream from, the treated field and might include impounded bodies such as ponds, lakes and reservoirs, or flowing waterways such as streams or rivers. For uses in coastal areas, aquatic habitat also includes marine ecosystems, including estuaries. Sulfur is insoluble in water; therefore, its use is not expected to result in exposure to aquatic ecosystems.

D. Assessment Endpoints

Assessment endpoints are defined as “explicit expressions of the actual environmental value that is to be protected.” Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (*i.e.*, a community of fish and aquatic invertebrates) and its attributes (*i.e.*, survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (*i.e.*, ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of

effects to characterize potential ecological risks associated with exposure to pesticides, such as sulfur.

To estimate exposure concentrations, the ecological risk assessment considers a single application at the maximum application rate to fields that have vulnerable soils. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, and reproduction studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants.

The submitted ecological toxicity data indicate that sulfur is practically nontoxic on an acute toxicity basis and all other ecological toxicity data were waived. An open literature search will be conducted to determine any additional relevant endpoints.

E. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

A conceptual model provides a written description and visual representation of the predicted relationships between sulfur, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (EPA, 1998).

1. Risk Hypothesis

For sulfur, the following ecological risk hypothesis is being employed for this baseline risk assessment:

Given the large annual sulfur usage and the high application rates, sulfur when used in accordance with the label, may result in potential adverse effects upon survival of non-target terrestrial organisms.

2. Conceptual Diagram

The conceptual site model is a generic graphic depiction of the risk hypothesis, and assumes that as an fungicide/ insecticide with a multi-site contact activity (disrupts

electron transport along the cytochromes) mode of action, sulfur, which has outdoor uses, is capable of affecting terrestrial and aquatic animals provided that environmental concentrations are sufficiently elevated as a result of proposed label uses. Through a preliminary iterative process of examining available data, the conceptual model (i.e., the representation of the risk hypothesis) has been refined to reflect the likely exposure pathways and the organisms that are most relevant and applicable to this assessment (Figure II.2). It includes the potential pesticide or stressor (sulfur), the sources and/ or transport pathways, exposure media, exposure points, biological receptor types, and attributes changes.

In the specific case of sulfur, the source and mechanism of release of the chemical may be applied by chemigation, soil band treatment (ground sprayer, aircraft), soil treatment (soil incorporation treatment), low volume spray concentrate (low volume ground concentrate), high volume spray or dilute (high volume ground sprayer), or dust (ground or aircraft) to an agricultural or ornamental plants field. Surface runoff from the areas of application is assumed to depend on factors such as topography, irrigation, and rainfall events; however, due to the fact that sulfur is insoluble in water, this compound is expected to runoff in large rain events (it is insoluble in water), possibly as eroded insoluble particles, depending on the application rate.

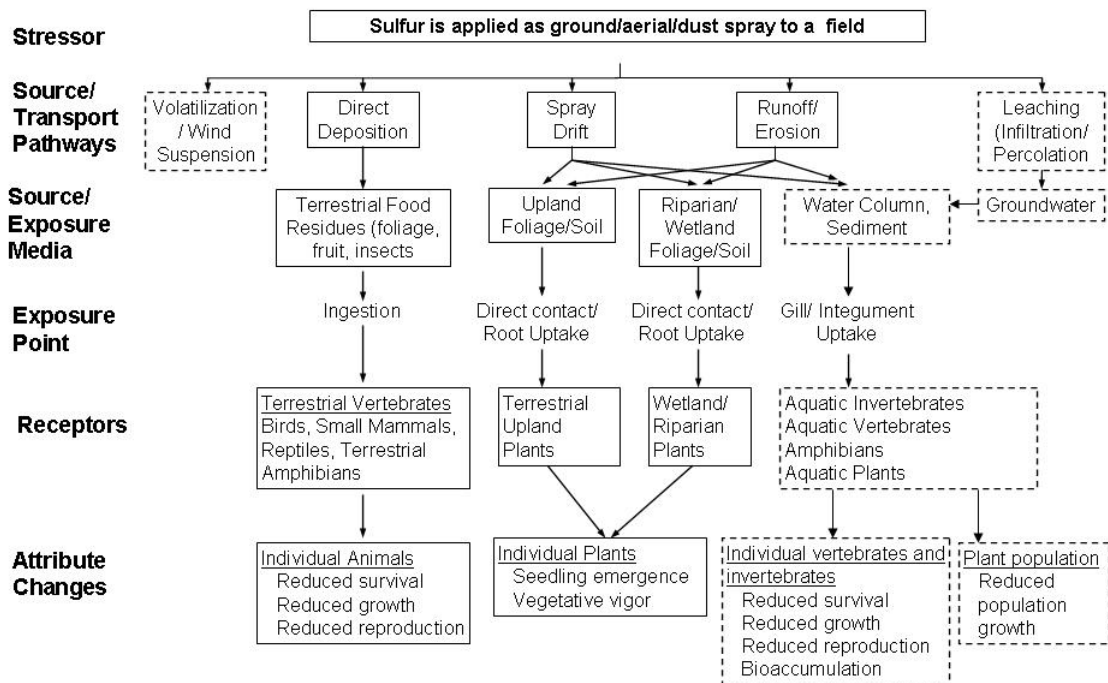
Additional transport mechanisms include spray drift and wind erosion (*e.g.*, when applied aerially), which may potentially transport contaminants to the surrounding sites. In addition, direct deposition may result in contamination of food items that may be consumed by terrestrial organisms. Sulfur is believed to be relatively reactive in soils with high bacteria population, where it is oxidized to a sulfate; therefore, long-term exposure of non-target organisms to sulfur is uncertain.

For aquatic receptors, the major point of exposure is through direct contact with the water column, sediment, and pore water (gill/ integument) contaminated with spray drift (from spray and aerial applications) and/ or runoff (which appears to be a minor route) from treated areas. Indirect effects to aquatic organisms (especially fish) can also occur through impact to various food chains. However, due to the fact that sulfur is insoluble in water, minimal exposure is expected. Sulfur exposure to terrestrial animals could occur through ingestion of contaminated food items such as grass, foliage, and small insects. Exposure to plants may occur mostly through direct contact, since root uptake is unlikely (due to low or no solubility of sulfur). On the other hand, root uptake of sulfate, the major derivative of sulfur, is beneficial to plants (this form of sulfur constitutes a needed nutrient to the plants).

Based on a review of the available data, it is hypothesized that terrestrial receptors may potentially be at risk from sulfur exposure. This is based on potential exposure due to the large application rates (ex. 122.5 lb a.i./A). The exposure to aquatic organisms is lower or minimal because sulfur is insoluble. The representative terrestrial receptors are certain mammals, birds and plants. The attribute changes used to assess risk for terrestrial receptors depend on the type of test (*e.g.*, reduced survival, growth, or reproduction). Although a full evaluation of risk to aquatic and terrestrial animals and plants was not possible due to the lack of a whole toxicity data set, based on the data available, it is not

expected that sulfur will be of any toxic concern. Sulfur appears to be relatively non-toxic.

Figure II.2. Ecological Conceptual Exposure Model for Screening-Level Risk Assessment of Sulfur Applied to Agricultural or Ornamentals Fields



F. Analysis Plan Options

1. Conclusions from Previous Risk Assessments

In 1991, a Reregistration Eligibility Document (RED) was issued for sulfur. At the time, it was concluded that since sulfur is a ubiquitous element in the environment and an essential nutrient for some organisms, it appears to pose a small hazard to non-target organisms. This is supported by data that shows low order of toxicity to various species tested. There was a concern that, upon oxidation, elemental sulfur forms sulfuric acid, which may acidify soil and water. At the time, it was recommended that lime, *i.e.* calcium carbonate, was applied, to neutralize the acidity produced by the sulfur. It was also concluded that elemental sulfur should not pose a problem to the environment because it rapidly incorporates into the natural sulfur cycle.

2. Preliminary Identification of Data Gaps

All environmental fate data requirements for sulfur are waived based on the availability of public information. The following notes were mostly taken from the 1991 RED.

Elemental sulfur, applied as pesticide or soil amendment, will become incorporated into the natural sulfur cycle. The fate of sulfur is dependent on environmental redox conditions. Under aerobic conditions, elemental sulfur is oxidized to SO_4^{2-} via microbial metabolism. The dissipation of SO_4^{2-} is dependent on leaching and soil organic matter immobilization. Under anaerobic conditions, elemental sulfur is reduced to S^{2-} via microbial metabolism. The subsequent fate of S^{2-} is dependent on metal sulfide precipitation or volatilization of H_2S . Therefore, elemental sulfur should not pose an environmental problem because it dissipates rapidly into the natural environment.

The major environmental concern with elemental sulfur is that upon oxidation it forms sulfuric acid, which can acidify soil or water ecosystems. In soil management systems, elemental sulfur is a common soil amendment used to acidify calcareous soil and increase the sulfur fertility; it is expected to have a similar effect when used as a pesticide. In soil and water management systems, the application of lime, *i.e.* CaCO_3 , is recommended to neutralize the acidity generated via sulfur oxidation.

Elemental sulfur dissipation requires, as a first step, usually, the sulfur oxidation, which depends to a high degree on the particle size distribution of the elemental sulfur; small particles will oxidize faster than larger particles. When sulfur is finely ground, and mixed with soil, it is oxidized to sulfate by soil microorganisms. Oxidation also depends on the microfloral population in soil, characteristics of the sulfur source, and the soil redox potential.

The total sulfur content in mineral soil, is approximately 700 $\mu\text{g/g}$. A large fraction of the soil sulfur is bound in soil organic matter (*e.g.* 95%); otherwise, the sulfur is in inorganic forms. The sulfur associated with soil organic matter can be roughly separated into humic acid bound sulfur (C-S bonding) and HI reducible S (sulfate esters and sulfamates). The cycling of organic sulfur components is dependent on mineralization via microbial exoenzyme (sulfohydrolases) or biological oxidation (respiration). Hence, in non-saline soil, organic matter cycling controls the sulfur chemistry.

The inorganic sulfur cycle is dependent on redox conditions. Sulfur can exist in nine different oxidation states, which range from S^{2-} to S^{6+} . In nature, the predominate sulfur species are sulfate (SO_4^{2-}) and sulfide (S^{2-} , HS^- and H_2S). The fate of elemental sulfur in aerobic environments is dependent upon oxidation to SO_4^{2-} via a microbially-mediated process. Elemental sulfur oxidation occurs when the redox potential exceeds a $\text{pe}+\text{pH}$ of 4. The oxidation of sulfur leads to formation of sulfuric acid, which may decrease the pH of some soils and shallow water bodies. Elemental sulfur, in fact, is used as a soil amendment to supplement sulfur fertility.

The dissipation of sulfate is dependent upon leaching and inorganic matter immobilization. In acid and near-neutral soils, sulfate can precipitate as gypsum ($\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$) when the soil solution SO_4^{2-} activity exceeds $10^{-2.5}$ M; however, in calcareous soil, gypsum precipitation requires a much higher soil solution SO_4^{2-} activity. Gypsum can be a persistent mineral in soils formed under semiarid to arid climatic conditions; otherwise, it is not expected to persist as a secondary soil mineral. Sulfate

can also be adsorbed to aluminum oxides and silicate clays by ligand binding (replacement of hydroxyl). These soil retention mechanisms, *e.g.*, precipitation and adsorption, cannot prevent SO_4^{2-} leaching. *Since sulfate is a ubiquitous species, it should not pose any environmental risk to ground or surface water pollution. In addition, microbes and plants can assimilate SO_4^{2-} with subsequent immobilization into organic compounds (cysteine, cystine, and methionine).*

No additional ecological effects data are required for sulfur. Sulfur is not soluble in water and the available data indicate low order toxicity to the four aquatic species tested. In addition to the fact that sulfur is ubiquitous in nature and chronic exposure is common, the available ecotoxicity data on terrestrial organisms indicate that sulfur is practically nontoxic on an acute basis. However, an open literature search will be completed to determine any additional relevant endpoints for non-target taxa.

Status of Data Requirements

Ecological Effects

The available ecotoxicity data on seven species suggest a low order of toxicity for sulfur. No additional data are required; however, an open literature search will be completed to determine any relevant endpoints for non-target taxa. If data are available, an evaluation will be made as to whether or not the data are adequate for use in a risk assessment. The Agency uses the ECOTOX database as its mechanism for searching the open literature. ECOTOX integrates three previously independent databases - AQUIRE, PHYTOTOX, and TERRETOX - into a system which includes toxicity data derived predominately from the peer-reviewed literature, for aquatic life, terrestrial plants, and terrestrial wildlife, respectively. At this point in time, a full and complete ECOTOX search has not been performed, but will be done prior to issuance of any Data Call-In.

Environmental Fate

All environmental fate data requirements for sulfur have been waived based on the availability of public information.

3. Measures of Effects and Exposure

The preliminary assessment of sulfur indicates that there is low risk associated with the use of sulfur. There is no evidence to suggest a hazard to the environment or to non-target organisms when this pesticide is used according to the label.

For a chemical, a number of measures of exposure are used, which are the measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint. Measures of exposure are potentially estimated using models. Aquatic exposure usually consists of aquatic EECs derived using a water-body that is vulnerable and representative of static ponds and first order waterways. Terrestrial exposure is usually estimated using a model that assumes a direct application to a variety of avian, mammal and reptilian food items. Exposure to terrestrial plants is usually

estimated using a model that assumes sulfur drifts or moves with runoff to adjacent habitats. Models require quantitative measurements for endpoints to evaluate the effects of the chemicals on the various species. In the absence of standard environmental fate studies, these measures of exposure could not be modeled.

Table II.4 provides a summary of the assessment endpoints previously identified as survival, growth and reproduction along with the measure of effects and exposure.

Table II.4. Measures of Ecological Effects and Exposure for Sulfur

Assessment Endpoint		Surrogate Species and Measures of Ecological Effect ¹	Measures of Exposure
Birds ²	Survival	Bobwhite acute oral LD ₅₀ (data waived) Bobwhite and mallard subacute dietary LC ₅₀ (Bobwhite quail LC ₅₀ >5620 ppm)	Maximum residues on food items (foliar)
	Reproduction and growth	Bobwhite and mallard chronic reproduction NOAEC and LOAEC (data waived)	
Mammals	Survival	Laboratory rat acute oral LD ₅₀ LD ₅₀ = >5g/kg	
	Reproduction and growth	Laboratory rat oral reproduction chronic NOAEC and LOAEC (data waived)	
Freshwater fish ³	Survival	Rainbow trout and bluegill sunfish acute LC ₅₀ (LC ₅₀ >180 ppm for rainbow trout and bluegill sunfish)	Peak EEC ⁴
	Reproduction and growth	Fathead minnow chronic (early life-stage) NOAEC and LOAEC (data waived)	60-day average EEC ⁴
Freshwater invertebrates	Survival	Water flea (and other freshwater invertebrates) acute EC ₅₀ . (Daphnia EC ₅₀ . >5,000)	Peak EEC ⁴
	Reproduction and growth	Water flea chronic (life cycle) LOAEC (data waived)	21-day average EEC ⁴
Estuarine/marine fish	Survival	Sheepshead minnow acute LC ₅₀ (data waived)	Peak EEC ⁴
	Reproduction and growth	Sheepshead minnow chronic (early life-stage) NOAEC and LOAEC (data waived)	60-day average EEC ⁴
Estuarine/marine invertebrates	Survival	Eastern oyster acute EC ₅₀ and mysid acute LC ₅₀ (Mysid shrimp LC ₅₀)	Peak EEC ⁴

Assessment Endpoint		Surrogate Species and Measures of Ecological Effect ¹	Measures of Exposure
		736 ppm)	
	Reproduction and growth	Mysid chronic NOAEC and LOAEC (data waived)	21-day average EEC ⁴
Terrestrial plants ⁵	Survival and growth	Monocot and dicot seedling emergence and vegetative vigor EC ₂₅ , EC ₀₅ , and NOAEC values (data waived)	Estimates of runoff and spray drift to non-target areas
Insects	Survival (not quantitatively assessed)	Honeybee acute contact LD ₅₀ (data waived)	Maximum application rate
Aquatic plants and algae	Survival and growth	Algal and vascular plant (i.e., duckweed) EC ₅₀ and NOAEC values for growth rate and biomass measurements (data waived)	Peak EEC

¹ If species listed in this table represent most commonly encountered species from registrant-submitted studies, risk assessment guidance indicates most sensitive species tested within taxonomic group are to be used for baseline risk assessments.

² Birds represent surrogates for amphibians (terrestrial phase) and reptiles.

³ Freshwater fish may be surrogates for amphibians (aquatic phase).

⁴ One in 10-year return frequency.

⁵ Four species of two families of monocots - one is corn, six species of at least four dicot families, of which one is soybeans. LD₅₀ = Lethal dose to 50% of the test population; NOAEC = No observed adverse effect concentration; LOAEC = Lowest observed adverse effect concentration; LC₅₀ = Lethal concentration to 50% of the test population; EC₅₀/EC₂₅ = Effect concentration to 50%/25% of the test population.

4. Endangered Species Considerations

Pesticide ecological risk assessments for registration review will address Endangered Species Act, Section 7 (a)(2) obligations. The data available on terrestrial species (mammalian, avian, honey bee) and aquatic species (rainbow trout, bluegill sunfish, daphnia, and mysid shrimp) indicate that sulfur is acutely nontoxic to these species. Sulfur use is not expected to pose an aquatic risk based on the results of available data on aquatic organisms and the insolubility of the compound. The use of sulfur is not expected to pose terrestrial risk based on available toxicity data results and the fact that sulfur in nature is ubiquitous therefore chronic exposure is common. An open literature search will be conducted to determine any survival, growth or reproductive endpoints.

Path Forward

The planned ecological risk assessment will evaluate the lines of evidence and make a determination of potential effects to endangered species. If the planned ecological risk assessment indicates that sulfur may affect, either directly or indirectly, listed species or affect critical habitat, the Agency will take steps to refine the assessment to determine whether this pesticide's uses are likely to adversely affect, or are not likely to adversely affect the species. In the case of critical habitat, the Agency will assess whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat.

If the Agency's assessment results in a determination that the pesticide may affect but is not likely to adversely affect a listed species or designated critical habitat, the Agency will request concurrence by the US Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS) (Services) on that determination. If the Services do not concur, the Agency will enter into Formal Consultation with them under the Endangered Species Act. If the Agency's assessment results in a determination that the pesticide is likely to adversely affect a listed species or designated critical habitat, the Agency will initiate Formal Consultation with the Services. Formal Consultation concludes with issuance of a Biological Opinion to the Agency. The Agency may seek to change the terms of registration to address unacceptable risks to a listed species should EPA determine such risks exist.

Other Information Needs

Information is requested for confirmation on the following label information:

1. use or potential use distribution (e.g., acreage and geographical distribution of relevant crops)
2. use history
3. median and 90th percentile reported use rates (lbs a.i./acre) from usage data – national, state, and county
4. application timing (date of first application and application intervals) by crop – national, state, and county
5. sub-county crop location data
6. usage/use information for non-agricultural uses (for example residential)
7. directly acquired county-level usage data (not derived from state level data)
 - a. maximum reported use rate (lb a.i./A) from usage data – county
 - b. percent crop treated – county
 - c. median and 90th percentile number of applications – county
 - d. total pounds per year – county
 - e. the year the pesticide was last used in the county/sub-county area
 - f. the years in which the pesticide was applied in the county/sub-county area
8. typical interval (days)
9. state or local use restrictions
10. ecological incidents not already reported to the Agency
11. monitoring data

The analysis plan will be revisited and may be revised depending upon the data available in the open literature and the information submitted by the public in response to the opening of the Registration Review docket.

Summary

- Sulfur is a fungicide/ insecticide with a multi-site contact activity mode of action (disrupts electron transport along the cytochromes).
- Sulfur accounts for 15% of the inner core of the earth and 0.052% of its crust. It is insoluble in water (HSDB).
- When sulfur is mixed with soil, it is oxidized to sulfate by soil microorganisms. Oxidation depends on the microfloral population in soil, characteristics of the sulfur source (particle size distribution), and environmental conditions in the soil.
- Since sulfate is a ubiquitous species, it should not pose any environmental risk to ground or surface water pollution. In addition, microbes and plants can assimilate SO_4^{2-} (sulfate) with subsequent immobilization into organic compounds.
- The Agency's Ecological Incident Information System (EIIS) does not contain any reports of damage or adverse effects to non-target organisms attributed to the use of sulfur.
- The fate data were waived for sulfur based on the availability of public information.
- Available ecotoxicity data suggest low toxicity to non-target aquatic and terrestrial organisms. All other ecotoxicity data requirements have been waived based on; 1) results of available data, 2) insoluble nature of sulfur in water; and 3) the fact that sulfur in nature is ubiquitous and chronic exposure is common.
- An open literature search will be completed to determine any relevant endpoints for non-target taxa.

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URLs:

<http://www.fotosearch.com/photos-images/sulfur.html>

Table I-1. Sulfur Table of Environmental Fate Data Requirements				
Guide-line #	Data Requirement	Study ID	Study Classification	Are Additional Data Needed for Risk Assessment?
161-1	Hydrolysis	No data	Waived ¹	no
161-2	Photolysis in Water	No data	Waived ¹	no
161-3	Photodegradation on Soil	No data	Waived ¹	no
161-4	Photodegradation in Air	No data	Waived ¹	no
162-1	Aerobic Soil Metabolism	No data	Waived ¹	no
162-2	Anaerobic Soil Metabolism	No data	Waived ¹	no
162-3	Anaerobic Aquatic Metabolism	No data	Waived ¹	no
162-4	Aerobic Aquatic Metabolism	No data	Waived ¹	no
163-1	Leaching-Adsorption/ Desorption	No data	Waived ¹	no
163-2	Laboratory Volatility	No data	Waived ¹	no
163-3	Field Volatility	No data	Waived ¹	no
164-1	Terrestrial Field Dissipation	No data	Waived ¹	no
164-2	Aquatic Field Dissipation	No data	Not required ²	no
164-3	Forestry Dissipation	No data	Not required ²	no
165-4	Accumulation in Fish	No data	Waived ¹	no
<p>1. The environmental fate data requirements were waived based on the availability of public information on this chemical. It is likely that sulfur would eventually react in the soil environments in the presence of soil microflora to form sulfate and enter the environment cycle.</p> <p>2. Data are not required because sulfur does not have aquatic uses.</p>				

Table I-2. Ecological Effects Data Requirements for Sulfur					
Guideline #	Data Requirement	Formulation	Are Additional Data Needed for Risk Assessment?	MRID or Acc. Number	Study Classification
71-1	Avian Acute Oral Toxicity	NA	No	No data submitted	N/A
71-2	Avian Subacute Dietary Toxicity	95% wettable powder formulation	No	GS0031-003	Satisfied
71-4	Avian Reproduction Toxicity	NA	No	No data submitted	N/A
72-1	Freshwater Fish LC ₅₀	99.5% dust formulation	No	GS0031-0004, GS0031-0005	Satisfied
72-2	Freshwater Invertebrate Acute LC ₅₀	90%	No	GS00031-0002	Satisfied
72-3(a)	Estuarine/Marine Fish LC ₅₀	NA	No	No data submitted	N/A
72-3(b)	Estuarine/Marine Invertebrate (Mollusk)	NA	No	No data submitted	N/A
72-3(c)	Estuarine/Marine Invertebrate (Mysid)	90%	No		Satisfied
72-3 (d)	Estuarine/Marine Crustacean	NA	No	No data submitted	N/A
72-4 (a)	Freshwater Fish Early Life-Stage	NA	No	No data submitted	N/A

Table I-2. Ecological Effects Data Requirements for Sulfur					
Guideline #	Data Requirement	Formulation	Are Additional Data Needed for Risk Assessment?	MRID or Acc. Number	Study Classification
72-4	Aquatic Invertebrate Life-Cycle (Freshwater) Chronic Toxicity	NA	No	No data submitted	N/A
72-4	Aquatic Invertebrate Life-Cycle (Marine) Chronic Toxicity	NA	No	No data submitted	N/A
72-5	Freshwater Fish Full Life-Cycle (marine)	NA	No	No data submitted	N/A
72-7	Aquatic Field Study	NA	No	No data submitted	N/A
141-1	Acute Honeybee Contact Toxicity Test	98%	No	05012143	Satisfied
141-2	Residues on Foliage Honeybee Toxicity Test	92%	No	05017101	Satisfied
141-4	Subacute Honeybee Feeding Toxicity Test	NA	No	No data submitted	

NA=Not Available; N/A=Not Applicable



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PC Code 016001, 016601, 076103,
076104, 129083
Case No. 0031, 4019, 4052
DP Barcode DP: 346318, 342928

MEMORANDUM

DATE: March 17, 2008

SUBJECT: Problem Formulation for Ecological Risk Assessment, for Carbon Dioxide and Gas Fumigant Producing Cartridges: Carbon, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur

FROM: José Luis Meléndez, Chemist *José Meléndez*
Jean Holmes, DVM, Risk Assessment Process Leader *Jean Holmes*
Environmental Risk Branch V
Environmental Fate and Effects Division (7507P)

THROUGH: Mah T. Shamim, Ph.D., Chief *Allen W. Vary*
Environmental Risk Branch V *03/18/08*
Environmental Fate and Effects Division (7507P)

TO: Veronique LaCapra, Chemical Review Manager
Jude Andreasen, Chemical Review Manager
Eric Miederhoff, Chemical Review Manager
Reregistration Branch II
Special Review and Reregistration Division

Please find attached the ecological risk assessment problem formulation for carbon dioxide and gas fumigant producing cartridges: carbon, sawdust, sodium nitrate, potassium nitrate and sulfur.

**Problem Formulation,
For Ecological Risk Assessment,
For Carbon Dioxide, and Gas Fumigant
Producing Cartridges: Sawdust, Sodium
Nitrate,
Potassium Nitrate and
Sulfur**

Case Number 4019, 4052, 0031

Environmental Fate and Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency



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Problem Formulation

The purpose of this problem formulation is to provide the foundation for the ecological risk assessment being conducted for carbon, sawdust, sodium nitrate, potassium nitrate and sulfur when used in fumigant gas producing cartridge products. It also includes carbon dioxide which has indoor fumigant uses. It does not include sulfur uses other than the gas cartridge use. It also does not include the active ingredient nitrite because there are no nitrite products registered at this time. As such, it articulates the purpose and objectives of the risk assessment, evaluates the nature of the problem, and provides a plan for analyzing the data and characterizing the risk (EPA, 1998).

A. Nature of Regulatory Action

This report summarizes the Environmental Fate and Effects Division's Problem Formulation for the Registration Review of; 1) carbon, carbon dioxide, and sawdust (Case Number 4019); 2) sodium and potassium nitrate (Case Number 4052); and 3) the cartridge use of sulfur (Case Number 0031). In 1991, the USEPA issued Reregistration Eligibility documents for carbon and carbon dioxide, sodium nitrate and potassium nitrate, and sulfur which serves as the basis for this assessment. At the time, sawdust was not included in the document. It was concluded that, for these chemicals, application of the cartridges to burrows (subsurface) precludes exposure to avian and aquatic organisms. However, organisms that live in burrows, including endangered species, may be impacted. The label as of the date of issuance of the RED documents included provisions to protect those species. For carbon dioxide, which only has indoor uses, the Agency concluded that exposure to non-target organisms was unlikely.

B. Stressor Source and Distribution

1. Nature of the Chemical Stressor

Carbon, sodium and potassium nitrates, sawdust, and sulfur are used in pyrotechnic fumigant gas producing cartridge products. After the cartridges are ignited they produce toxic gases that cause asphyxiation of the pests. These toxic gases, not the active ingredients, are the stressors for these products. Not all the gasses have been identified, however, for one product (Large Gas Cartridge, EPA Reg. No. 56228-21) over forty combustion products were identified, including carbon monoxide, carbon dioxide and nitrogen. For example, the following is a possible reaction (Savarie, *et.al.* 1980).



The gases displace the oxygen in the burrows, creating an un-breathable atmosphere, causing asphyxiation of the target organisms.

Carbon dioxide (CAS No. 124-38-9; PC Code 016601) is an insecticide gas used as an indoor fumigant. For this use, carbon dioxide is the stressor. Carbon dioxide is "poured" indoors as a fumigant in such places like sealed trucks, trailers, sealed railroad cars, food handling establishments and ships. The area to be fumigated is sealed, and the atmosphere is filled at a minimum of 60% carbon dioxide for up to 4-5 days, causing the

pests to die of asphyxiation. Table II.1 provides some basic characteristics of carbon dioxide.

Table II.1. Nature of the Chemical Stressor	
Common name	<i>Carbon Dioxide</i>
Chemical name	<i>Carbon Dioxide</i>
Pesticide type	<i>Insecticide, Rodenticide</i>
Chemical class	NA
CAS number	124-38-9
Empirical formula	CO ₂
Molecular mass (g/mol)	44.01
Vapor pressure	4.83x10 ⁴ mm Hg @ 25 deg C
Henry's Law Constant (atm-m ³ /mol)	NA
Solubility in water (g/L)	0.145 g/100 mL at 25°C
Log K _{ow}	NA
PK _a /PK _b	NA
Physical state	<i>Colorless odorless gas</i>
Melting point (°C)	-56.6 at 5.2 atm
Boiling point (°C)	-78.5
Density/Specific gravity (Air=1)	1.527
pH of saturated carbon dioxide solution	3.7 at 1 atm to 3.2 at 23.4 atm
Solubilities	<i>Miscible with hydrocarbons and most organic liquids</i>

Carbon dioxide is in the atmosphere; analyses of air in the temperate zones of the earth show 0.027-0.036% (v/v) of carbon dioxide (HSDB). Carbon dioxide is considered an inert ingredient without toxicological significance to non-target organisms in the environment.

2. Overview of Pesticide Usage

Table II.2 provides a summary of data regarding gas cartridge products containing sawdust, carbon, sodium nitrate, potassium nitrate, and sulfur as well as the carbon dioxide products. The table shows the labeled target organisms and the use sites. It is noted that sawdust and carbon products are co-formulated either with sodium or potassium nitrate and in various formulations with sulfur. The products consist of cartridges that are lit and inserted into the pests' burrows, where they are sealed. When the cartridges ignite, they produce toxic gasses which cause asphyxiation of the target pests (rodents and some larger mammals). These cartridges are to be used outdoors only (refer to use sites in Table II.2).

Carbon dioxide, used as a fumigant, is used to control a number of insects in enclosed indoor areas. These areas may contain grains or other agricultural commodities (food or feed crops, stored), as indicated in the table. Carbon dioxide may also be used in residential settings.

Table II.2. All Products Containing Carbon, Carbon Dioxide or Sawdust plus Sodium or Potassium Nitrate and Sulfur		
Product Name, Reg No.	Active Ingredients %	Target Species; Use Areas
SMOKE'em 4-463	Potassium nitrate 46.2% Sulfur 34.8% Sawdust 8.7%	Woodchucks, ground squirrels; Open fields, non-crop areas
Dexol Gopher Degasser 192-49	Potassium nitrate 45.0% Sulfur 45.0% Carbon 8.0%	Gophers, ground squirrels; Lawns, golf courses, gardens, rangeland
Revenge Rodent Smoke Bomb 9086-4	Potassium nitrate 38.8% Sulfur 39.4% Carbon 12.5%	Gophers, moles, woodchucks, rats, skunks, ground squirrels; Lawns, golf courses, non-crop areas, rangeland, meadows, reforested areas, open fields, parks
The Giant Destroyer 10551-1	Sodium nitrate 46.2% Sulfur 34.8% Carbon 8.7%	Gophers, moles, woodchucks, rats, skunks, ground squirrels; Lawns, golf courses, non-crop areas, rangeland, meadows, reforested areas, open fields
Large Gas Cartridge 56228-21	Sodium nitrate 53.0% Carbon (Charcoal) 28.0%	Coyotes, red foxes, striped skunks; In dens only in rangeland, crop and non-crop areas
Gas Cartridge 56228-2	Sodium nitrate 53.0% Carbon (Charcoal) 28.0%	Woodchucks, yellow bellied marmots, ground squirrels, black tailed prairie dogs, white tailed prairie dogs, Gunnison prairie dogs; Open fields, non-crop areas, rangeland, reforested areas, lawns, golf courses
Carbon dioxide 10330-20	Carbon dioxide 99.8%	Beetles, Psocoptera, moths; Storage, trucks, trailers, sealed railroad cars and ships. The following may be treated-raw and processed agricultural products such as corn, barley, oats, rice, sorghum, wheat, rye, cocoa and coffee beans, flour, cereal, dry beans, peas, pasta products, dry milk, nuts, dried fruits, tobacco products, spices and herbs, etc.
Carbon dioxide 38719-5	Carbon dioxide 99.95%	Silos, trucks, trailers, sealed railroad, cars, and ships, food handling establishments, processing and storage facilities and residential structures. The following raw agricultural commodities may be treated: wheat, oats, rice, barley, corn, processed food

There is no information on the typical usage (number of applications, “rate” or interval between applications) for carbon, carbon dioxide or sawdust. The state of California does report usage of these pesticides and some useful data may be extrapolated (refer to tables named Carbon Usage, Carbon Dioxide Usage and Sawdust Usage below). It is noted that the total usage of carbon decreased by almost one half from 2003 to 2004 in California and did not increase in 2005. Major decrease in use was in vertebrate control, followed by landscape maintenance. Another important use of carbon appeared to be rights of way. Data available for sawdust shows that less than 2 lb of the product were used in California in 2003 and 2004, and only 0.143 lb (total) were used in 2005. The carbon dioxide usage is higher than the one for carbon or sawdust. In California, the chemical total pounds range from 132,000 lb (in 2005) to 202,000 lb (in 2004). Major uses appear to be almond, dried fruit, grapes, pistachio, tomatoes and walnuts. With respect to fumigation of structures, food processing plants and structural pest control appeared to be the important categories, and a category named “fumigation, only.”

For sulfur, the California (CADPR) use information data indicate that there is an increasing trend on the use for “vertebrate control” in a period of three years, from 453 lb in 2003 to 4418 lb in 2005.

- There is also no information on the typical usage (number of applications, “rate” or interval between applications) for sodium nitrate and potassium nitrate. The Screening Level Usage Analysis (SLUA) was verified for these chemicals. The SLUA provides the average annual pounds of pesticide applied for each agricultural crop (*i.e.* for the states surveyed, not for the entire U.S.). According to the SLUA for sodium nitrate, it appears that crops of major use for the chemical are almonds, kiwifruit, nectarines, olives, pistachios and prunes & plums. In each case, <500 lb of active ingredient were used in California. However, it is indicated that ≥95% of the U.S. acres that have this gas cartridge use are in California. For potassium nitrate, the SLUA lists almonds, nectarines, pistachios and prunes & plums as the crops of interest, but <500 lb active ingredient were utilized in California. As in the previous case, it is indicated that ≥95% of the U.S. acres that have potassium nitrate gas cartridge use are in California.

Carbon Usage			
Publicly available data from the California Department of Pesticide Regulation was used to produce the following table outlining the pounds of carbon used in California over the three most recent years available (2003-2005).			
Crop/Area	2003 Lbs. Applied	2004 Lbs Applied	2005 Lbs. Applied
ALMOND	40	29	17
CHERRY		4	1
GRAPE			30
KIWI	0.1		
LANDSCAPE MAINTENANCE	283	145	110
LEMON	1		

NURSERY OUTDOOR TRANSPLANTS	2	3	
NURSERY GREENHOUSE TRANSPLANTS			2
NECTARINE			3
OAT (FORAGE - FODDER)		2	
PEAR	0.1	2	
PISTACHIO	28		18
RANGELAND		3	
REGULATORY PEST CONTROL	9	16	42
RESEARCH COMMODITY	0.01	0.03	
RIGHTS OF WAY	376	488	570
STRUCTURAL PEST CONTROL	3	1	2
UNCULTIVATED AG	9		
VERTEBRATE CONTROL	1,296	345	224
WALNUT	4	11	37
Chemical Total	2,051	1,047	1,056

Prepared by: Jenna Carter 7/31/07

Source: Cal DPR data - <http://www.cdpr.ca.gov/docs/pur/purmain.htm>

Carbon Dioxide Usage Publicly available data from the California Department of Pesticide Regulation was used to produce the following table outlining the pounds of carbon dioxide used in California over the three most recent years available (2003-2005).			
Site	2003 Pounds Applied	2004 Pounds Applied	2005 Pounds Applied
ALMOND	10,779	15,762	45,003
COMMODITY FUMIGATION	24,348	9,290	28,655
CORN, HUMAN CONSUMPTION		88	7
CORN (FORAGE - FODDER)	1,071		
DRIED FRUIT	7,988	6,877	3,785
FIG	152	613	157
FOOD PROCESSING PLANT	1,533	29,985	
FUMIGATION, OTHER	111,635	32,409	22,623
GRAPE	7,350	13,651	18,330
GRAPE, WINE	1,066	119	
LANDSCAPE MAINTENANCE		294	83
NUTS			923
PEAS			43
PISTACHIO	4,565	4,945	5,255
PUBLIC HEALTH			300
RICE		125	
RICE, WILD	8	22	39
RIGHTS OF WAY	698	41	

STORAGE AREA/BOX	183	267	411
STRUCTURAL PEST CONTROL	461	15,107	1,114
TOMATO	921	1,441	1,254
TOMATO, PROCESSING	421	1,127	902
UNKNOWN ¹	74	62,969	122
WALNUT	500	7,313	3,134
Chemical Total	173,757	202,446	132,139

¹ Site not specified in source data

Prepared by: Jenna Carter 6/29/07

Source: Cal DPR data - <http://www.cdpr.ca.gov/docs/pur/purmain.htm>

Sawdust Usage

Publicly available data from the California Department of Pesticide Regulation was used to produce the following table outlining the pounds of sawdust used in California over the three most recent years available (2003-2005).

Crop/Site	2003 Lbs. Applied	2004 Lbs. Applied	2005 Lbs. Applied
CHERRY			0.11
LANDSCAPE MAINTENANCE	0.4956	0.88	0.011
STRUCTURAL PEST CONTROL	0.12		
VERTEBRATE CONTROL	0.5412	0.5368	0.022
Chemical Total	1.1568	1.4168	0.143

Prepared by: Jenna Carter 8/01/07

Source: Cal DPR data - <http://www.cdpr.ca.gov/docs/pur/purmain.htm>

C. Receptors

1. Aquatic and Terrestrial Effects

The receptor is the biological entity that is exposed to the stressor (EPA, 1998). Various types of receptors may inhabit burrows, where carbon, sawdust, sulfur, sodium nitrate, and potassium nitrate are applied in the form of explosive cartridges. These include rodents and other small mammals. The areas to be fumigated are to be located outdoors only. In addition, several forms of life may be exposed to carbon dioxide, when it is applied to enclosed areas, such as ships, railroads, cars and storage facilities (may include insects, mites and rodents); however, these are usually considered the target pests, beetles, moths and other insects.

Consistent with the process described in the Overview Document (EPA, 2004), risk assessments use a surrogate species approach in its evaluation of pesticides such as carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate and sawdust.

Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) included under these taxonomic groupings. For the gas cartridge use of carbon, carbon dioxide, sawdust, sulfur, sodium nitrate and potassium nitrate all data requirements for ecological studies have been waived.

As indicated previously, the pest species are not exposed to the active ingredients in gas cartridges, but rather to the products of the pyrolysis. The cartridge application is subsurface into burrows, and exposure to aquatic organisms and most avian species is not anticipated. However, any organism living in or inhabiting burrows may be exposed and, thus, impacted and killed by the cartridges. There is a potential direct impact to non-target species and endangered species. To address the potential risks to non-target organisms, the Agency will review product efficacy data to ensure that labeling instructions are explicit concerning actions users must take before applying the product.

The potential direct effect of carbon dioxide on endangered species is minimal since it is utilized in enclosed structures, such as silos, trailers, food handling establishments, processing, storage facilities and residential structures.

Incident Reports

The Agency's Ecological Incident Information System (EIIS) does not contain any reports of damage or adverse effects to non-target organisms attributed to the use of carbon, sawdust, sulfur, sodium nitrate or potassium nitrate gas cartridge uses or carbon dioxide indoor fumigant uses. No incidents of contamination of surface, ground and drinking water have been reported to the Agency. A lack of reported incidents does not necessarily mean that such incidents have not occurred.

2. Ecosystems Potentially at Risk

The ecosystems at risk are often extensive in scope, and as a result it may not be possible to identify specific ecosystems during the development of a baseline risk assessment. However, in general terms, terrestrial ecosystems potentially at risk could include the treated field and areas immediately adjacent to the treated field that may receive drift or runoff (note that these are not routes of dissipation for the carbon, sawdust, sodium nitrate, potassium nitrate, and sulfur gas cartridge use or the indoor carbon dioxide fumigant use). The gas cartridges may be used in sealed burrows in such areas as open fields, non-crop areas, rangeland, reforested areas, lawns and golf courses; however, this will result in limited exposure. Areas adjacent to the treated field could include cultivated fields, fencerows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats and other uncultivated areas. Carbon dioxide is used in enclosed areas; therefore, there are no extensive terrestrial ecosystems at risk.

Aquatic ecosystems potentially at risk include water bodies adjacent to, or down stream from, the treated field and might include impounded bodies such as ponds, lakes and reservoirs, or flowing waterways such as streams or rivers. For uses in coastal areas,

aquatic habitat also includes marine ecosystems, including estuaries. The use of carbon dioxide is not expected to result in exposure to aquatic ecosystems because it is used in enclosed areas and the sealed burrow application of carbon, sawdust, sodium nitrate, potassium nitrate, and sulfur gas cartridge is also not expected to result in exposure to aquatic ecosystems. No extensive exposure is anticipated if used according to the label.

D. Assessment Endpoints

Assessment endpoints are defined as “explicit expressions of the actual environmental value that is to be protected.” Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (*i.e.*, a community of fish and aquatic invertebrates) and its attributes (*i.e.*, survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (*i.e.*, ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to pesticides, such as carbon, carbon dioxide, sodium nitrate, potassium nitrate, sulfur and sawdust.

To estimate exposure concentrations, the ecological risk assessment considers a single application at the maximum application rate to fields that have vulnerable soils. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, and reproduction studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants.

Registrant submitted ecological toxicity data were waived for carbon, carbon dioxide, sodium nitrate, potassium nitrate, sulfur and sawdust based on the gas cartridge uses and the indoor fumigant uses. No additional data is required to determine relevant endpoints. The registrant has submitted ecological toxicity data for sulfur to support the non-gas cartridge uses.

E. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a

pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

A conceptual model provides a written description and visual representation of the predicted relationships between carbon, sulfur, sodium nitrate, potassium nitrate, carbon dioxide and/or sawdust, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (EPA, 1998).

1. Risk Hypothesis

For carbon, sawdust, sulfur, sodium nitrate, potassium nitrate and carbon dioxide, the following ecological risk hypotheses are being employed for this baseline risk assessment:

Carbon, sawdust, sodium nitrate, potassium nitrate, sulfur and sawdust by-products from gas cartridge use, when used in accordance with the label, result in potential adverse effects upon the survival of non-target terrestrial organisms.

Carbon dioxide, when used in accordance with the label, does not result in potential adverse effects to non-target terrestrial and aquatic organisms.

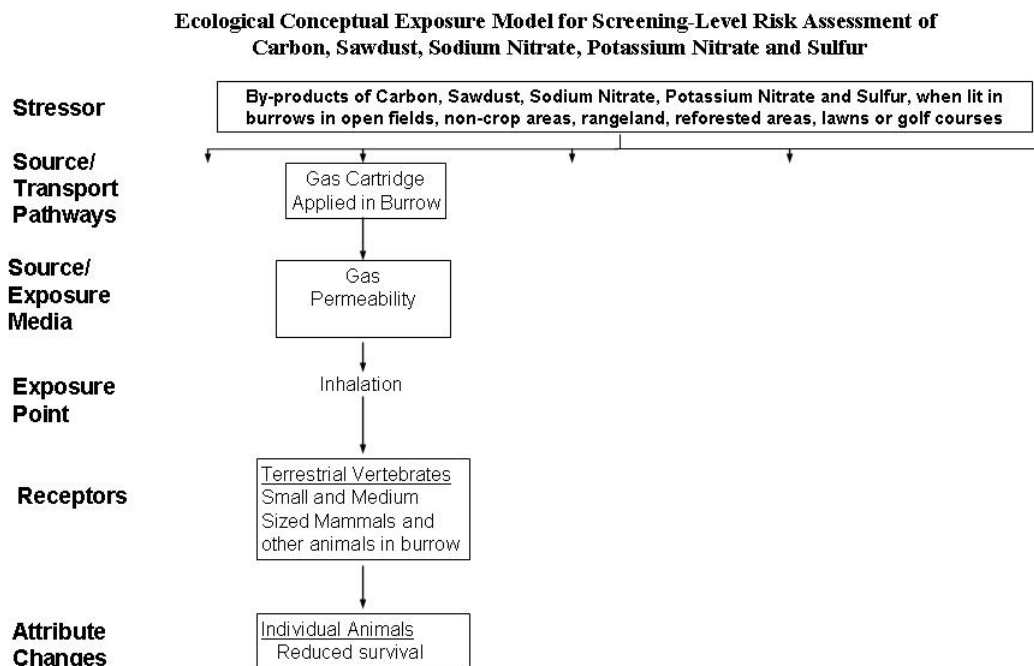
2. Conceptual Diagram

The conceptual site model is a generic graphic depiction of the risk hypothesis, and assumes that as rodenticides/ predacides with a inhalation toxic mode of action, carbon, sulfur, sodium nitrate, potassium nitrate and sawdust by-products are capable of affecting terrestrial (and less likely aquatic) animals provided that environmental concentrations are sufficiently elevated as a result of proposed label uses. However, through a preliminary iterative process of examining available data, the conceptual model (i.e., the risk hypothesis) has been refined to reflect the likely exposure pathways and the organisms that are most relevant and applicable to this assessment (Figure II.1). It includes the potential stressor (reaction by-products from the gas cartridge use, *e.g.* carbon monoxide, carbon dioxide and nitrogen), the source and/or transport pathways, exposure media, exposure point, biological receptor types, and attributes changes.

The stressor resulting from application of gas cartridges applied to sealed burrows in open fields, rangelands, lawns, golf courses, non-crop areas or reforested areas are gases that are formed after the explosion of the cartridges, including carbon monoxide. The exposure media/ source is gas permeability, that is, carbon monoxide and other gases that may be inhaled by terrestrial animals that inhabit burrows, resulting in death by asphyxiation (the attribute change is reduced survival). Since the instructions of these cartridges indicate that the burrows are to be sealed quickly after the cartridge is activated and inserted in burrow, the gases are to remain for an extended period inside the burrow,

and the exposure to non-target animals is expected to be minimal, except for animals living in burrows.

Figure II.1. Conceptual Diagram for Carbon, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur Risk to Terrestrial Animals



F. Analysis Plan

1. Conclusions from Previous Risk Assessments

In 1991, Re-registration Eligibility Documents for carbon and carbon dioxide, potassium nitrate and sodium nitrate, and for sulfur were issued and covered various products containing these chemicals. The general conclusion is that there are no unreasonable effects to the environment due to the use of these active ingredients. The use of carbon, potassium nitrate, sodium nitrate, and sulfur could result in potential impact to certain endangered species, while carbon dioxide is an indoor use only fumigant with limited exposure potential.

2. Preliminary Identification of Data Gaps and Analysis Plan-Need uses

All the environmental fate and ecological effects data requirements are waived for carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate and sawdust for the gas cartridge uses. The waivers were based on the ecological effects assessment of carbon, sulfur, sodium nitrate, potassium nitrate and sawdust, the fact that some of these chemicals are widespread and/or the physical and chemical properties are understood. Carbon dioxide has only indoor uses. For indoor uses, usually, only hydrolysis is required; however, since carbon dioxide is a gas at room temperature, the data requirement is also waived.

All the ecological effects data requirements are waived for gas cartridge uses of carbon, carbon dioxide, sawdust, sulfur, sodium nitrate and potassium nitrate. The cartridges are applied to burrows, subsurface, which precludes substantive exposure to avian and aquatic organisms or terrestrial organisms that do not live in burrows. However, organisms that live in burrows may be at risk. A review of gas cartridge efficacy data will be conducted to ensure there is appropriate labeling language regarding timing of application and observation of signs indicating the presence or absence of target and non-target organisms.

Status of Data Requirements

Ecological Effects

All ecological effects data requirements for carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate and sawdust have been waived for the gas cartridge use. Efficacy data on the gas cartridges will be evaluated.

Environmental Fate

All environmental fate data requirements for carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate and sawdust have been waived.

3. Measures of Effects and Exposure

Ecological effects data are waived. The preliminary assessment of carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate, and sawdust indicates that they are chemically un-reactive in the environment. There is no evidence to suggest a hazard to the environment when these pesticides are used according to the label. However, any non-target organism inhabiting a burrow in which the gas cartridges are applied would potentially be adversely affected.

For a chemical, a number of measures of exposure are used, which are the measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint. Measures of exposure are potentially estimated using models. Aquatic exposure usually consists of aquatic EECs based on a total residue approach and derived using a water-body that is vulnerable and representative of static

ponds and first order waterways. Terrestrial exposure is usually estimated using a model that assumes a direct application to a variety of avian, mammal and reptilian food items. Exposure to terrestrial plants is usually estimated using a model that assumes that a chemical drifts or moves with runoff to adjacent habitats. Models require quantitative measurements for endpoints to evaluate the effects of the chemicals on the various species. In the absence of fate data, these measures of exposure could not be modeled.

Table II.5 provides a summary of the assessment endpoints previously identified as survival, growth and reproduction along with the measure of effects and exposure. No registrant submitted data to support the gas cartridge or indoor fumigant use are available for the measures of effects.

Table II.5. Measures of Ecological Effects and Exposure for Carbon, Carbon Dioxide, Sulfur, Sodium Nitrate, Potassium Nitrate, and Sawdust

		Surrogate Species and Measures of Ecological Effect ¹	Measures of Exposure
Birds ²	Survival	Bobwhite acute oral LD ₅₀ Bobwhite and mallard subacute dietary LC ₅₀ (data waived)	Maximum residues on food items (foliar)
	Reproduction and growth	Bobwhite and mallard chronic reproduction NOAEC and LOAEC (data waived)	
Mammals	Survival	Laboratory rat acute oral LD ₅₀ (data waived)	
	Reproduction and growth	Laboratory rat oral reproduction chronic NOAEC and LOAEC (data waived)	
Freshwater fish ³	Survival	Rainbow trout and bluegill sunfish acute LC ₅₀ (data waived)	Peak EEC ⁴
	Reproduction and growth	Fathead minnow chronic (early life-stage) NOAEC and LOAEC (data waived)	60-day average EEC ⁴
Freshwater invertebrates	Survival	Water flea (and other freshwater invertebrates) acute EC ₅₀ (data waived)	Peak EEC ⁴
	Reproduction and growth	Water flea chronic (life cycle) LOAEC (data waived)	21-day average EEC ⁴
Estuarine/marine fish	Survival	Sheepshead minnow acute LC ₅₀ (data waived)	Peak EEC ⁴
	Reproduction and growth	Sheepshead minnow chronic (early life-stage) NOAEC and LOAEC (data waived)	60-day average EEC ⁴
Estuarine/marine invertebrates	Survival	Eastern oyster acute EC ₅₀ and mysid acute LC ₅₀ (data waived)	Peak EEC ⁴

		Surrogate Species and Measures of Ecological Effect ¹	Measures of Exposure
	Reproduction and growth	Mysid chronic NOAEC and LOAEC (data waived)	21-day average EEC ⁴
Terrestrial plants ⁵	Survival and growth	Monocot and dicot seedling emergence and vegetative vigor EC ₂₅ , EC ₀₅ , and NOAEC values (data waived)	Estimates of runoff and spray drift to non-target areas
Insects	Survival (not quantitatively assessed)	Honeybee acute contact LD ₅₀ (data waived)	Maximum application rate
Aquatic plants and algae	Survival and growth	Algal and vascular plant (i.e., duckweed) EC ₅₀ and NOAEC values for growth rate and biomass measurements (data waived)	Peak EEC

¹ If species listed in this table represent most commonly encountered species from registrant-submitted studies, risk assessment guidance indicates most sensitive species tested within taxonomic group are to be used for baseline risk assessments.

² Birds represent surrogates for amphibians (terrestrial phase) and reptiles.

³ Freshwater fish may be surrogates for amphibians (aquatic phase).

⁴ One in 10-year return frequency.

⁵ Four species of two families of monocots - one is corn, six species of at least four dicot families, of which one is soybeans. LD₅₀ = Lethal dose to 50% of the test population; NOAEC = No observed adverse effect concentration; LOAEC = Lowest observed adverse effect concentration; LC₅₀ = Lethal concentration to 50% of the test population; EC₅₀/EC₂₅ = Effect concentration to 50%/25% of the test population.

4. Endangered Species Considerations

Pesticide ecological risk assessments for registration review will address Endangered Species Act, Section 7 (a)(2) obligations. Data requirements were waived for carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate, and sawdust for the gas cartridge use; therefore no RQs can be calculated to assess the risk to endangered species. At this time, no incident reports are available that indicate risk to endangered species.

All the labels for carbon, sulfur, sodium nitrate, potassium nitrate, and sawdust gas cartridge products have an “Endangered Species Considerations” section, in which it is specified that the product should not be used in the presence of specified endangered species. Additional specifications, such as time of the year during which the product should or should not be used, temperature, etc. may appear in some labels.

Path Forward

The Agency realizes that when the gas cartridges are used, any organism in a properly treated burrow will likely be killed and is concerned about potential impact to populations of non-target and endangered species. Due to the potential risk to non-target organisms, the Agency will review product efficacy data. This information will be used to ensure that label instructions are explicit concerning actions users must take before applying the products. It may require more extensive labeling regarding timing of application and observation of signs indicating the presence or absence of target and non-target organisms.

The planned ecological risk assessment will evaluate the lines-of-evidence and make a determination of potential effects to endangered species. If the planned ecological risk assessment indicates that carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate and sawdust may affect, either directly or indirectly, listed species or affect critical habitat, the Agency will take steps to refine the assessment to determine whether this pesticide's uses are likely to adversely affect, or are not likely to adversely affect the species. In the case of critical habitat, the Agency will assess whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat.

If the Agency's assessment results in a determination that the pesticide may affect but is not likely to adversely affect a listed species or designated critical habitat, the Agency will request concurrence by the USFWS and NMFS (Services) on that determination. If the Services do not concur, the Agency will enter into Formal Consultation with them under the Endangered Species Act. If the Agency's assessment results in a determination that the pesticide is likely to adversely affect a listed species or designated critical habitat, the Agency will initiate Formal Consultation with the Services. Formal Consultation concludes with issuance of a Biological Opinion to the Agency. The Agency may seek to change the terms of registration to address unacceptable risks to a listed species should EPA determine such risks exist.

Other Information Needs

Information is requested for confirmation on the following label information:

1. confirmation on the following label information
 - g. maximum application rates
 - h. frequency of application, application intervals, and maximum number of applications per season
 - i. geographic limitations on use
2. use or potential use distribution (e.g., acreage and geographical distribution of relevant crops)
3. use history
4. median and 90th percentile reported use rates (lbs ai/acre) from usage data – national, state, and county

5. application timing (date of first application and application intervals) by crop – national, state, and county
6. sub-county crop location data
7. usage/use information for non-agricultural uses (e.g., forestry, residential, rights-of-way)
8. directly acquired county-level usage data (not derived from state level data)
 - j. maximum reported use rate (lbs ai/acre) from usage data – county
 - k. percent crop treated – county
 - l. median and 90th percentile number of applications – county
 - m. total pounds per year – county
 - n. the year the pesticide was last used in the county/sub-county area
 - o. the years in which the pesticide was applied in the county/sub-county area
9. typical interval (days)
10. state or local use restrictions
11. ecological incidents not already reported to the Agency
12. monitoring data

The analysis plan will be revisited and may be revised depending upon the information submitted by the public in response to the opening of the Registration Review docket. is not expected to be a risk issue to humans based currently registered use patterns.

Summary

- Carbon dioxide is a naturally occurring substance; analyses of air in the temperate zones of the earth show 0.027-0.036% (v/v) of carbon dioxide (HSDB). Carbon, sawdust, sulfur, potassium nitrate, sodium nitrate, and carbon dioxide are considered ingredients without toxicological significance to non-target organisms in the environment.
- The state of California reports usage of carbon, carbon dioxide and sawdust and useful data may be extrapolated. The total usage of carbon decreased by almost one half from 2003 to 2004 and did not increase in 2005. Major decrease in use was in vertebrate control, followed by landscape maintenance. Data available for sawdust shows that only 0.143 lb (total) were used in 2005. In California, the carbon dioxide total pounds range from 132,000 lb (in 2005) to 202,000 lb (in 2004). Major uses appear to be almond, dried fruit, grapes, pistachio, tomatoes and walnuts.
- The California (CADPR) use information data for sulfur indicate that there is an increasing trend on the use for “vertebrate control” in a period of three years, from 453 lb in 2003 to 4418 lb in 2005.
- According to the SLUA for sodium nitrate, it appears that crops of major use for the chemical are almonds, kiwifruit, nectarines, olives, pistachios and prunes & plums. In each case, <500 lb of active ingredient were used in California. However, it is indicated that ≥95% of the U.S. acres are in California. For potassium nitrate, the SLUA lists almonds, nectarines, pistachios and prunes & plums as the crops of interest, but <500 lb active ingredient were utilized in California. As in the previous case, it is indicated that ≥95% of the U.S. acres are in California.
- All the environmental fate data requirements are waived for carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate and sawdust. The fate data are waived based on the ecological effects assessment of the chemicals, and the fact that some of these chemicals are widespread or natural chemicals and the physical and chemical properties

of the chemicals are understood. Carbon dioxide has only indoor uses. Usually, only hydrolysis is required; however, since carbon dioxide is a gas at room temperature, the data requirement is also waived.

- All the ecological effects data requirements are waived for carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate and sawdust for the gas cartridge use. The ecological requirements for carbon, sulfur, sodium nitrate, potassium nitrate and sawdust are waived based on the lack of exposure to most non-target organisms and the fact that any non-target organism inhabiting a properly treated burrow with the gas cartridges would be killed. Furthermore, carbon dioxide, a naturally occurring gas, is used indoors only. No exposure to non-target organisms is anticipated.
- Efficacy data will be reviewed for the gas cartridge uses to determine if label language needs to be revised.
- The Agency's Ecological Incident Information System (EIIIS) does not contain any reports of damage or adverse effects to non-target organisms attributed to the use of carbon, carbon dioxide, sulfur, sodium nitrate, potassium nitrate or sawdust.

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Table 1. Carbon, Carbon Dioxide, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur Table of Environmental Fate Data Requirements for Gas Cartridge and Indoor Fumigant Use

Guide-line #	Data Requirement	Study ID	Study Classification	Are Additional Data Needed for Risk Assessment?
161-1	Hydrolysis	No data	Waived ¹	no
161-2	Photolysis in Water	No data	Waived ¹	no
161-3	Photodegradation on Soil	No data	Waived ¹	no
161-4	Photodegradation in Air	No data	Waived ¹	no
162-1	Aerobic Soil Metabolism	No data	Waived ¹	no
162-2	Anaerobic Soil Metabolism	No data	Waived ¹	no
162-3	Anaerobic Aquatic Metabolism	No data	Waived ¹	no
162-4	Aerobic Aquatic Metabolism	No data	Waived ¹	no
163-1	Leaching-Adsorption/ Desorption	No data	Waived ¹	no
163-2	Laboratory Volatility	No data	Waived ¹	no
163-3	Field Volatility	No data	Waived ¹	no
164-1	Terrestrial Field Dissipation	No data	Waived ¹	no
164-2	Aquatic Field Dissipation	No data	Not required ²	no
164-3	Forestry Dissipation	No data	Not required ²	no
165-4	Accumulation in Fish	No data	Waived ¹	no
<p>1. Data requirements were waived for carbon, sawdust, sodium nitrate and potassium nitrate based on the limited exposure that is expected to non-target organisms when used according to label specifications. These pesticides are applied in cartridges in sealed burrows. Carbon dioxide data requirements were also waived based on no exposure due to indoor only uses. Carbon, sawdust and carbon dioxide are considered inert ingredients without toxicological significance to non-target organisms in the environment.</p> <p>2. Data are not required because carbon, sawdust, sodium nitrate, potassium nitrate and sulfur do not have aquatic uses; carbon dioxide only has indoor uses.</p>				

Table I-2. Ecological Effects Data Requirements for Carbon, Carbon Dioxide, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur for Gas Cartridge and Indoor Fumigant Use

Guideline #	Data Requirement	Formulation	Are Additional Data Needed for Risk Assessment?	MRID or Acc. Number	Study Classification
71-1	Avian Acute Oral Toxicity	NA	No	No data submitted	N/A
71-2	Avian Subacute Dietary Toxicity	NA	No	No data submitted	N/A
71-4	Avian Reproduction Toxicity	NA	No	No data submitted	N/A
72-1	Freshwater Fish LC ₅₀	NA	No	No data submitted	N/A
72-2	Freshwater Invertebrate Acute LC ₅₀	NA	No	No data submitted	N/A
72-3(a)	Estuarine/Marine Fish LC ₅₀	NA	No	No data submitted	N/A
72-3(b)	Estuarine/Marine Invertebrate (Mollusk)	NA	No	No data submitted	N/A
72-3(c)	Estuarine/Marine Invertebrate (Mysid)	NA	No	No data submitted	N/A
72-3 (d)	Estuarine/Marine Crustacean	NA	No	No data submitted	N/A
72-4 (a)	Freshwater Fish Early Life-Stage	NA	No	No data submitted	N/A

Table I-2. Ecological Effects Data Requirements for Carbon, Carbon Dioxide, Sawdust, Sodium Nitrate, Potassium Nitrate and Sulfur for Gas Cartridge and Indoor Fumigant Use

Guideline #	Data Requirement	Formulation	Are Additional Data Needed for Risk Assessment?	MRID or Acc. Number	Study Classification
72-4	Aquatic Invertebrate Life-Cycle (Freshwater) Chronic Toxicity	NA	No	No data submitted	N/A
72-4	Aquatic Invertebrate Life-Cycle (Marine) Chronic Toxicity	NA	No	No data submitted	N/A
72-5	Freshwater Fish Full Life-Cycle (marine)	NA	No	No data submitted	N/A
72-7	Aquatic Field Study	NA	No	No data submitted	N/A
141-1	Acute Honeybee Contact Toxicity Test	NA	No	No data submitted	N/A
141-2	Residues on Foliage Honeybee Toxicity Test	NA	No	No data submitted	N/A
141-4	Subacute Honeybee Feeding Toxicity Test	NA	No	No data submitted	N/A

NA=Not Available; N/A=Not Applicable

IV. Human Health Effects Scoping Document



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Date: January 17, 2008

SUBJECT: Sulfur (PC code 077501). Human Health Risk Scoping Document in Support of Registration Review. DP Barcode 346937.

FROM: Yan Donovan, Risk Assessor
Health Effects Division (7509P)
Office of Pesticide Programs

Handwritten signature of Yan Donovan in black ink.

THRU: Ray Kent, Branch Chief
Susan Hummel, Senior Scientist
Reregistration Action Branch 4
Health Effects Division (7509P)
Office of Pesticide Programs

Handwritten signature of Ray Kent in black ink.

TO: Veronique LaCapra
Chemical Review Manager
Special Review and Reregistration Division (7508P)
Office of Pesticide Programs

Executive Summary

Health Effects Division's (HED) sulfur scoping team has completed the human health risk assessment status update for sulfur as part of the Registration Review process. Sulfur is an insecticide/miticide/fungicide which is currently registered for use on a variety of field crops, fruits, vegetables, ornamentals, lawns, and golf courses. The most recent and comprehensive risk assessment for sulfur was conducted in 1990 associated with the reregistration of sulfur. Based on the natural occurrence of sulfur in food and in the environment, it was determined that "sulfur is recognized as safe for use as a pesticide and, is exempted from tolerances...". Therefore, no dietary, residential, or aggregate risk assessment was conducted. No subchronic or chronic toxicity studies are available. Acute toxicity is low. Acute oral toxicity is category IV, while acute dermal and inhalation are category III. Sulfur is an eye and skin irritant (Category III). It is not a skin sensitizer. In response to California incident data, a qualitative occupational risk assessment was conducted previously which recommended that a 24-hour re-entry interval be established for foliar applications, and that workers wear personal protective equipment such as coveralls, chemical-resistant gloves, and goggles during mixing/loading and application. Sulfur was also assessed as a member of the "weathered materials" inert ingredients by the Inert Ingredient Focus Group in 2002 and classified as

List 4A. The exemption from the requirement of a tolerance for sulfur was reassessed at that time.

HED's scoping team concludes that no new dietary or aggregate risk assessment is needed for the Registration Review of sulfur. However, due to the large number of reported incidents associated with sulfur product uses, especially incidents related to respiratory problems, a refined incident report is needed to analyze the relationship between the nature of incidents and the types of products used. A new ORE assessment is needed for the Registration Review of sulfur. Depending on the outcome of the refined incident report, a subchronic inhalation study may be required to assess risk to handlers, and additional PPE such as respirators may be needed for some sulfur product labels.

Introduction

HED has evaluated the status of the human health assessments for sulfur to determine whether sufficient data are available and whether a new human health risk assessment is needed to support Registration Review. HED has considered the most recent risk assessments for sulfur, HED database, OPPIN database, and Google online search during the process of this scoping. For a complete listing of the references, see Section **Reference** at the end of this memo.

Elemental sulfur is an insecticide/miticide/fungicide which is currently registered for use on a variety of field crops, fruits, vegetables, ornamentals, lawns, and golf courses. It is formulated into dusts (20-99.8% ai), wettable powders, and flowable concentrates. Sulfur is also mixed with other pesticides/compounds and formulated into liquids or powders. There are several registered products where sulfur is mixed with potassium nitrate and carbon. These sulfur, potassium nitrate and carbon mixtures are designed to undergo chemical reactions and produce toxic fumes after ignition. Although no toxicity data are available on the fume by products, HED believes that worker and bystander exposure scenarios are not likely to exist based on the use patterns (underground uses) and current label precautions. This scoping document is for sulfur active ingredient only.

Hazard Identification/Toxicology

No subchronic or chronic toxicity studies are available for elemental sulfur. Acute oral toxicity is category IV, while acute dermal and inhalation are category III. Sulfur is an eye and skin irritant (Category III). It is not a skin sensitizer.

Conclusions: The HED registration review scoping team determined that since sulfur is exempted from the requirement of tolerances on food commodities due to its natural occurrence in food and its abundance in the environment, and that any sulfur absorbed into the body is metabolized to harmless products, risk to human health from dietary exposure is likely to be minimal. However, inhalation risks to workers and home owners during mixing, loading, and applying have not been assessed before. Depending on the out come of the refined incident report, a subchronic inhalation study may be required for the Registration Review of sulfur to assess risk to handlers.

Exposures

It was determined previously that “sulfur is recognized as safe for use as a pesticide and, is exempted from tolerances. Information from Canada indicates that the use of sulfur on raw agricultural commodities and food or feed items in that country is exempt from the requirements of tolerance and that the use of sulfur according to good agricultural practices is recognized as safe...” (HED memo of 09/10/1990, L. Kutney), therefore, no dietary assessment was conducted.

Conclusions: The HED registration review scoping team concurs with the previous decision that no tolerance is needed for sulfur, due to its natural occurrence in food and its abundance in the environment. In addition, sulfur is practically insoluble in water, so bioavailability of the element from food and water to human is not expected to be great. Small amounts of sulfur in the intestinal tract will be converted to sulfide, which will be excreted as sulfate. In humans, normal sulfur excretion as sulfate is 0.6-1.4 g sulfur/day and normal blood serum contains 0.8-1.4 mg/100 mL sulfur as sulfate (Agency memo of 02/04/1976, M. H. Rogoff). No dietary assessment is needed. However, depending on the out come of the refined incident report, inhalation data to assess risk to handlers may be needed.

Aggregate

No aggregate risk assessment has been conducted previously.

Conclusions: HED’s scoping team concurs with the previous decision that an aggregate risk assessment is not needed for Registration Review of sulfur.

Incident Report

The active ingredient responsible for the largest numbers of acute occupational pesticide related illnesses in the 1998-1999 Sensor data, was sulfur (78 cases, MRID 46654303 in reference #8). Most were farm workers performing routine work activities that did not involve pesticide application. A separate incident report being prepared by HED indicates that there are incidents associated with the use of products containing elemental sulfur as the sole active ingredient.

Conclusions: HED’s scoping team concludes that a refined incident report is needed to analyze the relationship between the nature of incidents involving elemental sulfur and the types of product used, so that appropriate protective/precaution statements can be added to the labels of those products that caused high number of incidents, and at the same time, allow the Agency to determine if additional data are required to assess risks to handlers.

Occupational Exposure and Risk

A partial, qualitative occupational risk assessment was conducted previously which recommended that a 24-hour re-entry interval for foliar applications be established and that workers should wear personal protective equipment such as coveralls, chemical-resistant gloves, and goggles during mixing/loading and application based on California incident data (HED memo of 07/20/1990, P. Perreault).

Conclusions: HED's scoping team concludes that all label requirements previously recommended have been adequately incorporated into the most current sulfur product labels. However, the previously conducted qualitative partial occupational risk assessment is no longer adequate. A new occupational risk assessment is needed for the Registration Review of sulfur. Depending on the outcome of the refined incident report, a subchronic inhalation study may be required to assess risk to workers. Additional PPE such as respirators may be needed for some sulfur product labels based on the outcome of the upcoming analysis of the incident data.

Conclusions/Future Actions Needed

- A new ORE assessment is needed for the Registration Review of sulfur.
- Inhalation endpoint selection may be needed.

Data Requirements

- A subchronic inhalation study may be required to assess risk to handlers.
- Additional PPE such as respirators may be needed for some sulfur product labels based on the outcome of the upcoming analysis of the incident data.

References

- 1) Bibliography for Sulfur (OPPIN database);
- 2) Agency memo of 01/31/2002, K. Boyle, "Meeting of the IIFC Decision Memo";
- 3) HED memo of 09/10/1990, L. Kutney, TXR Nos. 008104, CASwell # 812, "FY 1990 Reregistration of Sulfur; Toxicology, Product and Residue Chemistry, Reentry and Nondietary Exposure Issues";
- 4) HED memo of 07/25/1990, W. Greear, "Toxicology Summary for the FY'90 Reregistration Decision on Sulfur";
- 5) HED memo of 07/20/1990, P. Perreault, "Assessment of Reentry/Non-Dietary Exposure Data Requirements for Sulfur and Recommendations for the Reregistration Decision Document";
- 6) Agency memo of 02/04/1976, M. H. Rogoff, "Waiver of Data- Elemental Sulfur";
- 7) HED memo of 01/13/1982, C. Trichilo, "Sulfur registration Standard".
- 8) MRID 46654303 Calvert, G.; Plate, D.; Das, R.; et. al. (2004) Acute occupational pesticide-related illness in the US, 1998-1999: Surveillance findings from the SENSOR-Pesticides Program. American Journal of Industrial Medicine 45: 14-23.

V. GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
ACGIH	American Conference of Governmental Industrial Hygienists
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
DCI	Data Call-In
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC ₅₀	50% Effect Concentration
ECOTOX	An EPA database for locating chemical toxicity data for aquatic life, terrestrial plants and wildlife
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EUP	End-Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
FWP	Final Work Plan
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HIARC	Hazard Identification Assessment Review Committee
IR	Index Reservoir
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter

MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
MUP	Manufacturing-Use Product
NA	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
OSHA	Occupational Safety and Health Administration
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
PWP	Preliminary Work Plan
Q ₁ *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TLV	Threshold Limit Value
TREX	Terrestrial Residue EXposure model
TWA	Time Weighted Average
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 13 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: An Overview of the Benefits of Sulfur Use on Agricultural Crops (DP 417520)

FROM: Tara Chandgoyal, Ph. D., Plant Pathologist
Biological Analysis Branch

Tara Chandgoyal

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Arnet Jones

Diann Sims, Chief
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Timothy Kiely, Chief
Economic Analysis Branch
Biological and Economic Analysis Division (7503P)

Timothy Kiely

TO: Jose Gayoso, Chemical Review Manager
Risk Management and Implementation Branch 2
Pesticide Re-evaluation Division (7508P)

Product Review Panel: April 30, 2014

SUMMARY

This document qualitatively characterizes the benefits of sulfur used on agricultural crops. Sulfur is registered for dozens of major and minor uses (field crops, vegetable crops, fruits/nuts and berries, and ornamentals) as a fungicide/miticide for the control of fungal diseases and mites. Historically, sulfur has been heavily used in the United States on grapes, tomatoes, peaches,

oranges, apples, cherries, and carrots for control of fungal powdery mildew disease and mites. Sulfur is a valuable pesticide in managing plant diseases because of its low cost and good efficacy. It plays an important role in pest resistance management because no fungal pest has been reported to have resistance to sulfur. It plays an important role in integrated pest management in organic crop production. Sulfur has been used for decades on many crops giving growers extensive experience and knowledge of its use as a pesticide.

BACKGROUND

As part of the registration review process, the Environmental Fate and Effects Division (EFED) conducted a risk assessment that found some crops (some varieties of gooseberries, currants, apricots, raspberries, and cucurbits) may be adversely affected by sulfur applications. In addition, the risk assessment document also mentioned that there are five known incidents of unsubstantiated toxicity of sulfur to some crops (such as cucurbits and berries). This document provides an overview of the benefits of sulfur use on agricultural crops and its role in pest management.

ANALYSIS

In evaluating the benefits of a pesticide to the user, BEAD considers a number of factors. The most direct benefit of a pesticide is its ability to control pests that would otherwise damage a crop, reducing the yield and/or the quality of the produce. A pesticide might also provide value to a grower if it provides similar pest control at lower cost than other control measures. BEAD also considers less tangible benefits, including the role a pesticide may play in resistance management or in integrated pest management (IPM) programs.

Sulfur is a natural element used for centuries to control plant diseases and mites (Browde and Ohmart, 2001). The top 10 (in terms of average lbs a.i. applied per year) sulfur use crops are listed in Table 1 (EPA BEAD, 2014). Sulfur is effective in controlling powdery mildew disease and mites on various crops. Powdery mildew and mites can cause heavy crop losses under pest favorable weather conditions and are the primary target pests for sulfur applications. Table 1 also shows that sulfur is an inexpensive fungicide compared to most of its alternatives. Although comparative efficacy of alternatives was not considered in this analysis, the percent of crop treated with sulfur indicates grower reliance on it for pest management (Table 1).

Table 1: High Sulfur Use Crops with Disease/Pest Controlled (2004-2012) and Average Cost of Alternatives.

Crop	Major Diseases/Pests ¹	Average Pounds a.i. Applied ²	Average Percent Crop Treated ²	Sulfur Average Cost (\$) / Acre ³	Alternatives Average Cost (\$) / Acre ^{3,4}
Grapes	Powdery Mildew, Bud Mite, Blister Mite	38,900,000	80	3	22
Tomatoes	Powdery Mildew, Mites	8,900,000	60	10	15
Peaches	Powdery Mildew, Brown Rot, Leaf Spot, Silver Mite	2,400,000	60	5	20
Oranges	Mites	1,400,000	10	11	28
Apples	Powdery Mildew, Scab, Blister Mite,	1,300,000	30	7	21
Cherries	Powdery Mildew, Brown Rot, Leaf Spot, Mite	1,000,000	45	6	23
Carrots	Powdery mildew, Mites	1,000,000	45	7	13
Grapefruit	Mites	800,000	45	11	23
Pistachios	Citrus Flat Mite	700,000	30	11	25
Strawberry	Powdery Mildew, Red Spider Mite	600,000	50	3	44

1 Pest listed as controlled by sulfur on product labels

2 Data sources include:

USDA-NASS (United States Department of Agriculture's National Agricultural Statistics Service), 2004-2012

EPA Proprietary Data, 2004-2012

California DPR (Department of Pesticide Regulation), 2004-2012

3 EPA Proprietary Data, 2008-2012.

4 Costs of alternatives are for target pest listed in this table. The costs of alternatives are a simple average across the nine years for the listed target pests.

The Fungicide Resistance Action Committee (FRAC, 2012) has designated sulfur as FRAC Code M2 and is the only chemical in the group. Sulfur has multi-site contact activity - belonging to the target site and code “multi-site contact activity,” and group name and chemical group “inorganic”. It is considered as a low risk group for resistance development, without any signs of resistance developing to this fungicide.

The use of inorganic fungicides (such as sulfur, copper) has been well documented in the literature (Elis and Bradley, 1992). Beckman (2008) stated, “Sulfur is the oldest recorded fungicide and has been used for more than 2,000 years, early in agriculture history, the Greeks recognized its efficacy against rust on wheat. Sulfur can be used as a preventative fungicide against powdery mildew, rusts and other diseases. Sulfur prevents fungal spores from germinating, so it should be applied before the disease development”. Sulfur label states that it can be phytotoxic to cucurbits and some varieties of berries when temperatures are high. Beckman (2008) and others recommend against using sulfur when temperatures are expected to

exceed 80°F to reduce the risk of plant phytotoxicity. This may be the reason for five known incidents of unsubstantiated toxicity of sulfur to crops as mentioned above. It is also documented that certain varieties of gooseberries, currants, apricots, raspberries, and cucurbits are susceptible to sulfur phytotoxicity.

Sulfur has no known resistance by any pest. It plays an important role in integrated pest management and resistance management. Sulfur is used by organic crop growers because it is effective in controlling fungal diseases and mite pests on various crops. Organic crop growers use sulfur in managing crop pests on different crops. Organic crop growers use various cultural practices to reduce pest pressure and they have a limited number of compounds (such as copper based fungicides, potassium bicarbonate, and biological fungicides such as *Ampelomyces quisqualis*) for controlling pests (Anomynous, 2014). Therefore, sulfur plays an important role in the integrated management of pests in organic production of different crops.

CONCLUSION

Sulfur is an inorganic pesticide that plays an important role in plant disease/pest management on many major and minor use crops because it provides effective control of both fungal diseases and mites at low cost. It also plays an important role in pest resistance management because no pest has been reported to be resistant to sulfur and can be rotated with other compounds that are prone to resistance. Sulfur is important for the organic growers because of a limited number of compounds available (such as copper and biologicals) for controlling pests on these crops.

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Browde, J and Ohmart, C. 2001. Improving sulfur management. Accessed on February 3, 2014. <http://www.practicalwinery.com/mayjun01p11.htm>

Ellis, B.W and Bradley, F.M. 1992. The organic Gardner's Handbook of Natural Inset and Disease Control, Rodale Press. Emmaus, PA. 534pp.

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Proposed Decision Framework for Assessing Risks of Pesticides to Honey Bees

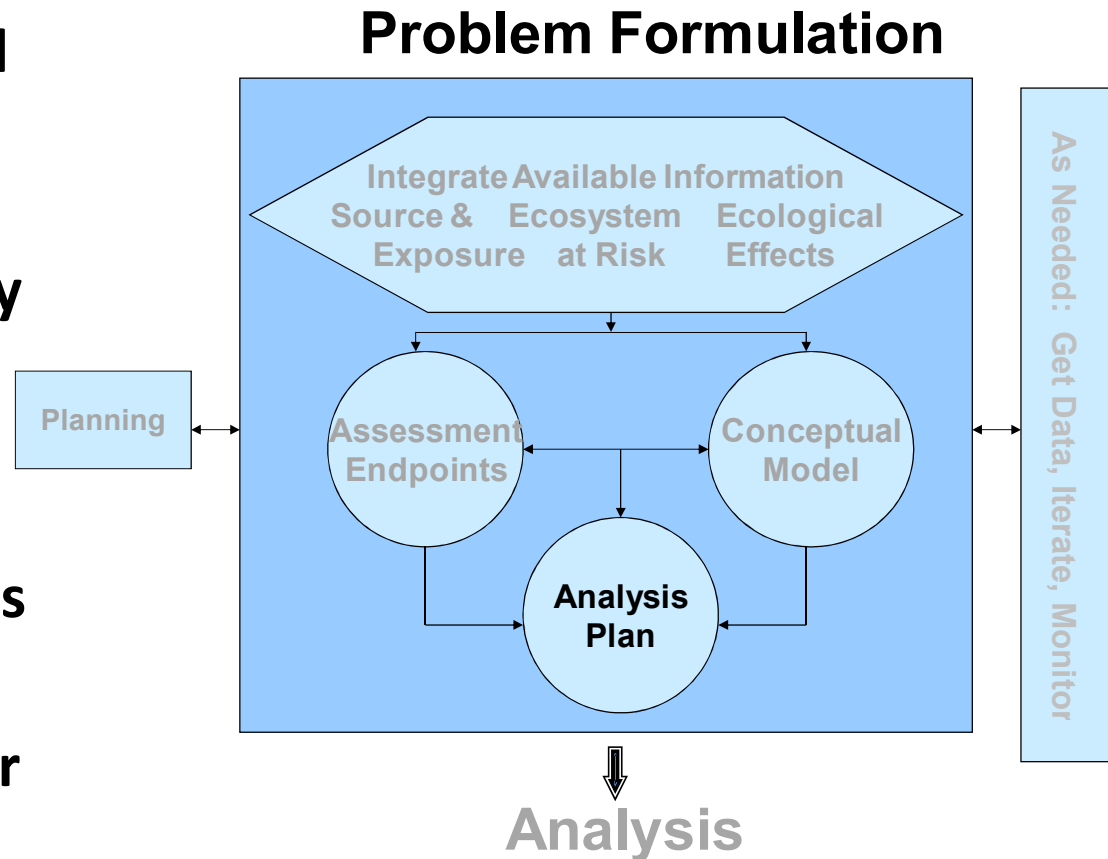
Keith Sappington, M.S.

Environmental Fate and Effects Division

Office of Pesticide Programs

Outline

1. **Attributes of Proposed Process**
2. **Process for Foliar Spray Applications**
3. **Process for Soil/Seed Treatment Applications**
4. **Comparison with other published risk assessment schemes**



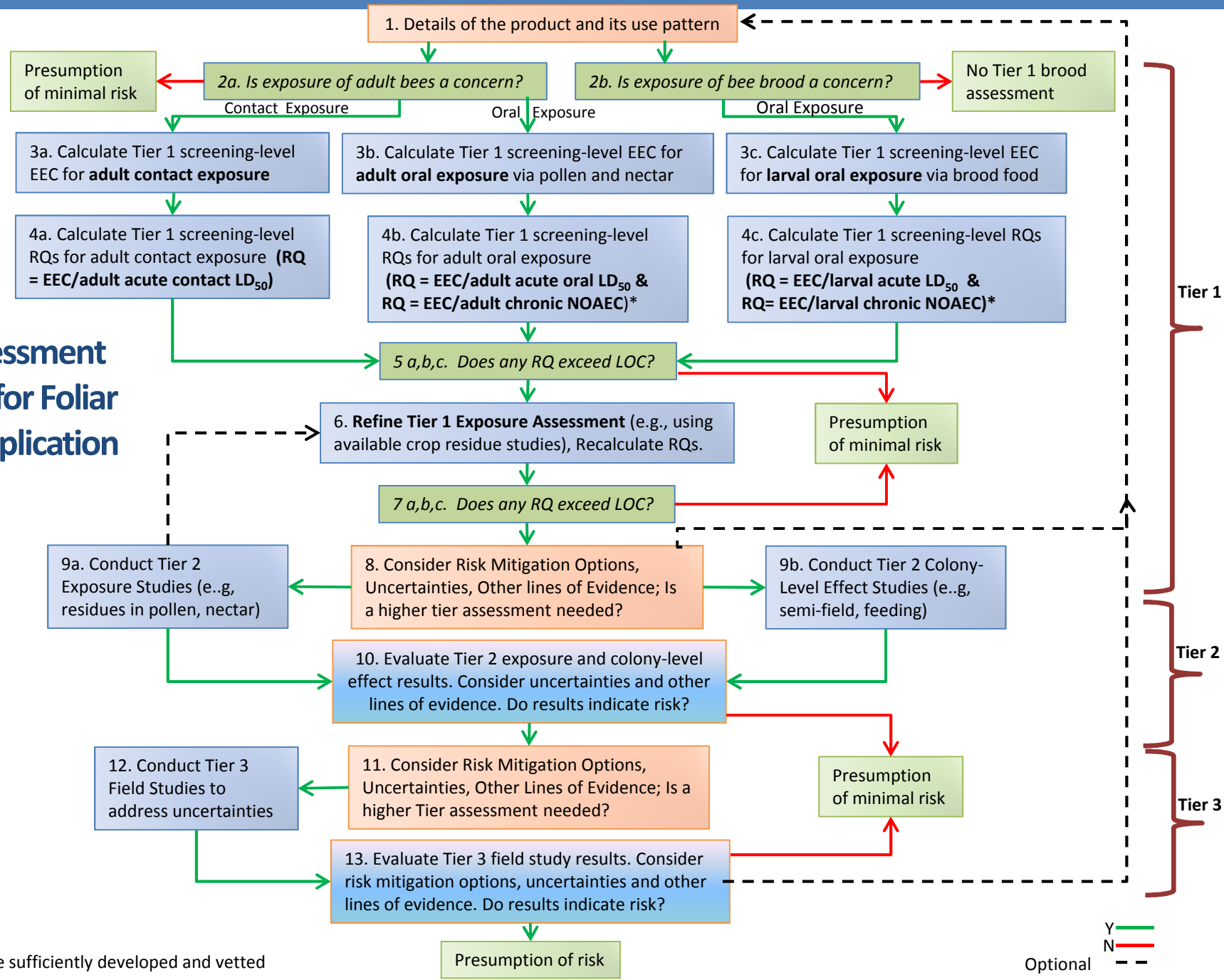
Attributes of Proposed Decision Framework

- **Three risk assessment ‘tiers’**
 - Tier 1 = screening level assessment (conservative, quantitative, individual-level effects)
 - Tiers 2 and 3 = increasing information needs (greater realism, refined estimates of exposure, risk characterized at colony level)
- **Relies largely on guideline studies (and recommends several in development)**
- **Focuses on major (and quantifiable) exposure pathways of concern**
- **Separate process for foliar vs. soil/seed treatment applications**
- **Decisions consider multiple lines of evidence and uncertainty**

Application of Proposed Decision Frameworks

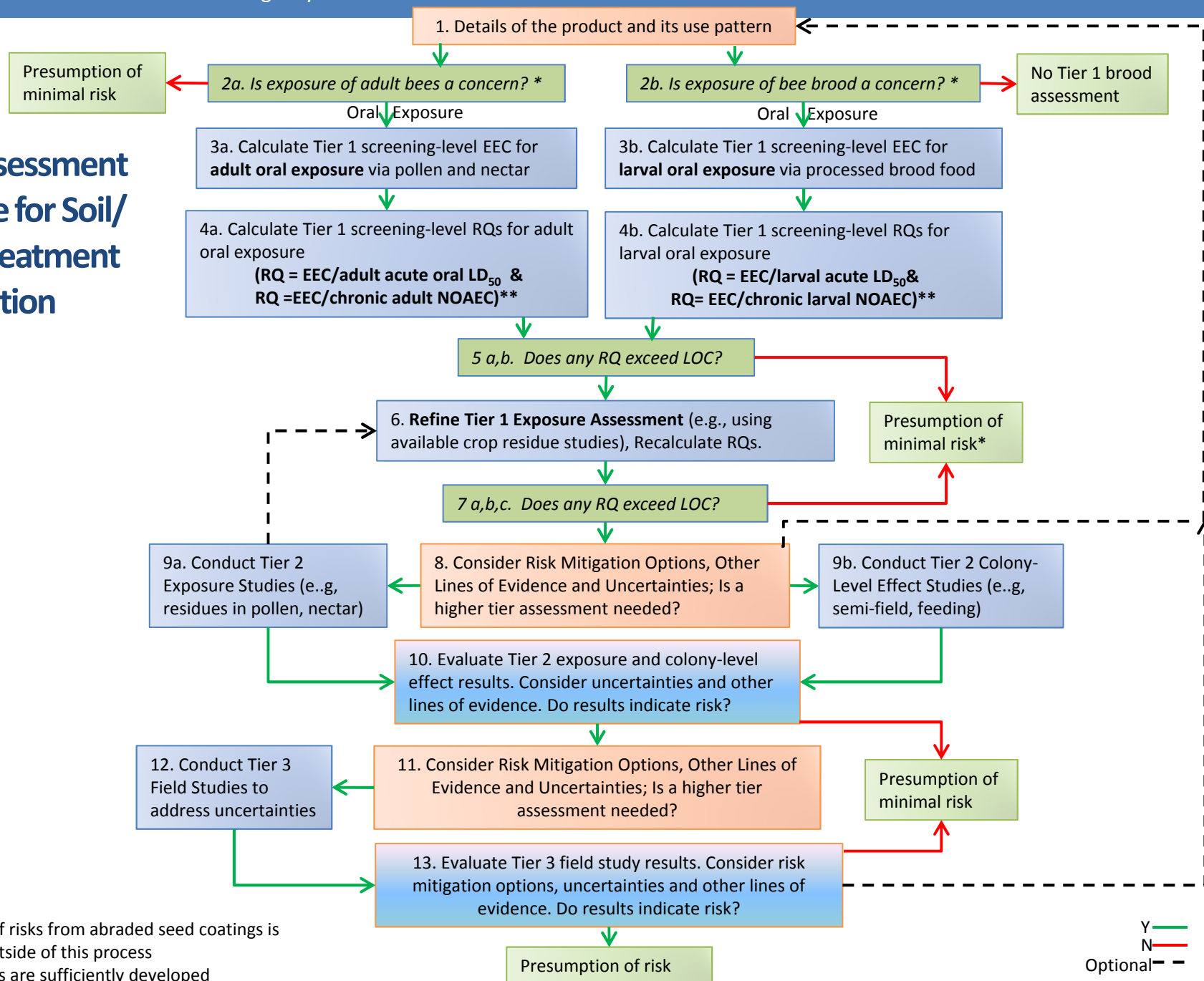
- **New vs. existing pesticides**
- **Iterative nature of assessments**
- **Framework flexibility**
- **Future modifications**

Risk Assessment Scheme for Foliar Spray Application



* When tests are sufficiently developed and vetted

Risk Assessment Scheme for Soil/Seed Treatment Application



*Mitigation of risks from abraded seed coatings is addressed outside of this process

** When tests are sufficiently developed

Comparison to Other Risk Assessment Schemes

- European Food Safety Authority (EFSA 2012)
- Society of Environmental Toxicology and Chemistry “Pellston” Workshop (Fischer and Moriarty 2011)
- **Some Similarities:**
 - All involved tiered processes (effects at the individual level, then at the colony level)
 - Different schemes depending on application method (foliar spray, soil, seed treatment)
 - Contact and oral are dominant routes of exposure
 - All recognize need for acute and chronic effects to be assessed initially
- **Some Differences:**
 - Decision “triggers” take various forms (when specified)
 - Non-*Apis* bees are included in EFSA (2012) and Fischer and Moriarty (2011), although full implementation will require additional research and test development.
 - Risk conclusions at higher tiers consider multiple lines of evidence, (White Paper); other schemes rely on outcome of semi field or field studies

Tier I Exposure Refinements & Tier II Tools for Assessing Exposure of Bees to Pesticides

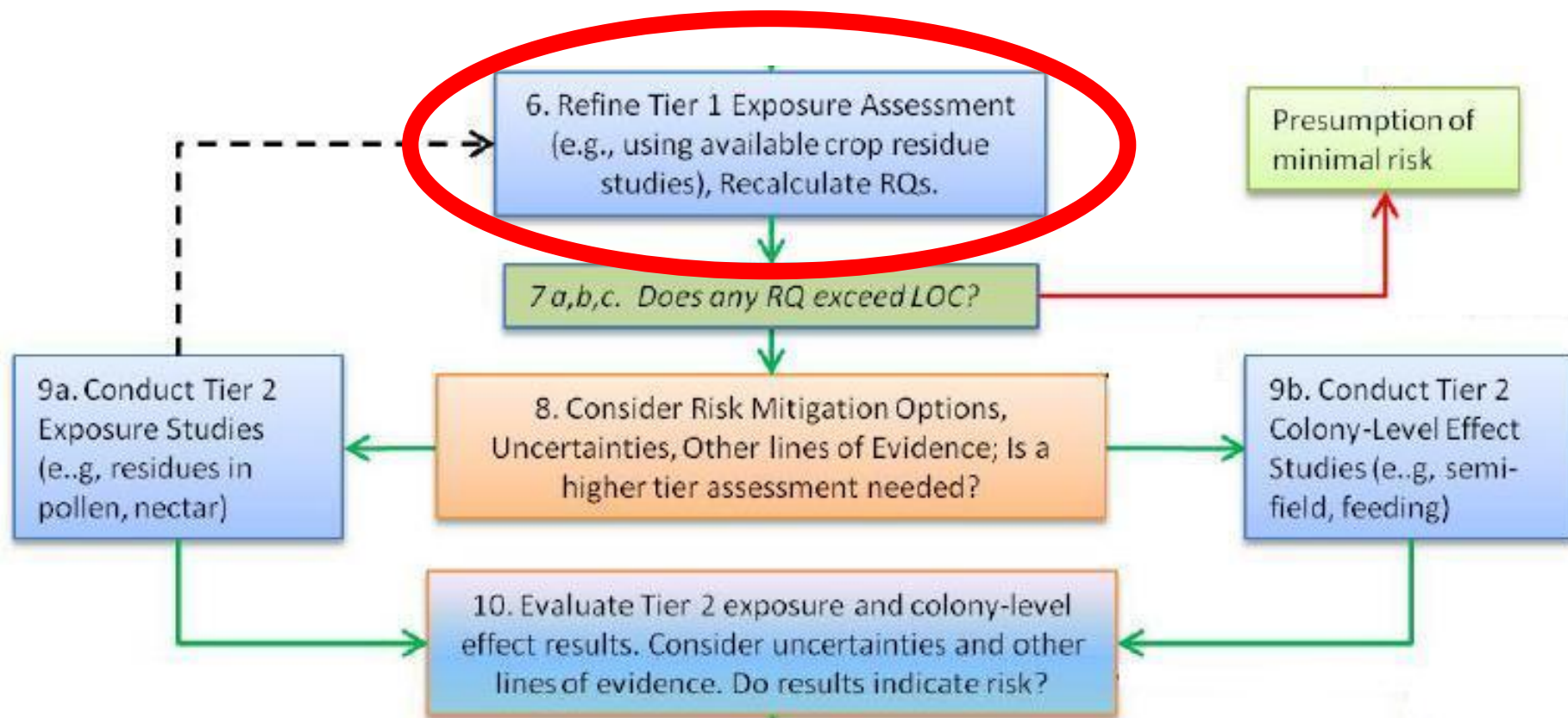
Reuben Baris, M.S.

Environmental Fate and Effects Division

Office of Pesticide Programs

Outline

- Options for refining Tier I exposure estimates when the screen identifies chemicals that need additional evaluation
- Tier II exposure study descriptions



Potential Tier I Exposure Refinements

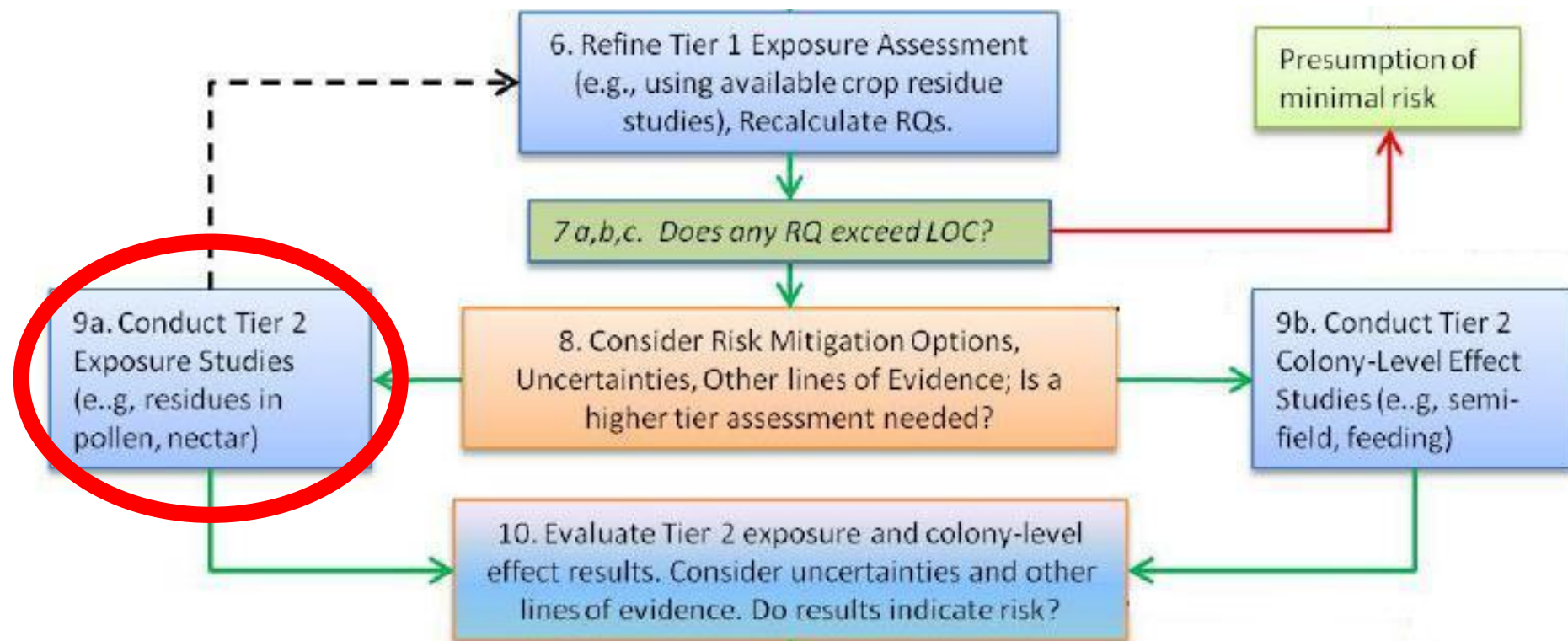
- Purpose: provide an additional level of realism for conservative Tier I estimates.
- Empirical data that are routinely submitted as part of registration package that could be use to refine Tier I exposure estimates
- Refinement options are based on available data already submitted to fulfill data requirements under FIFRA
- Refinements for dietary exposure only
 - Refinements are based on studies conducted on food commodities
 - No guideline studies are currently available to provide additional information for contact exposure
- If Dietary AND Contact exposure exceed the LOC, a higher tier analysis is needed.

Potential Tier I Exposure Refinements

Study Type	Foliar Applications	Soil Applications
Cropped Terrestrial Field Dissipation (TFD; OCSPP 835.6100)	X	X
Crop Field Trial (Magnitude of Residue Studies; OCSPP 860.1500)	X	X
Accumulation in Rotational Crops (OCSPP 860.1850)	--	X
Nature of Residue (Plant Metabolism Studies; OCSPP 860.1300)	--	X
Plant Uptake and Translocation Test (OCSPP 850.4800)	X	X

Tier II Exposure Studies

Purpose: obtain chemical specific, empirically-based exposure data relevant to bees in the field.



Tier II Exposure Studies: Objectives

- Reducing uncertainty by using empirical data
 - Addressing Tier I assumptions (*e.g.*, concentrations in tall grass = nectar and pollen, consumption rates)
 - Exposure on intended use sites, methods, and patterns
- Exposures are quantified through direct spray and diet
 - Shift focus from individual bee to whole colony
 - Residues may be measured in pollen, nectar, on bees, and/or hive products
- Goal is to complete Tier II studies in a manageable way to obtain desired information on bee exposure
 - Balancing certainty and uncertainty

Tier II Exposure Studies: Limitations

- Goal is to gather important information on chemical specific bee exposure in the field
- Uncertainties/Considerations
 - In-hive residues may be different than those encountered by bees in the field
 - Addressing Tier I uncertainties – unprocessed food sources
 - Time and resource allocation
 - Unknown if residues in leaves and flowers are a conservative measure of residues in pollen and nectar

Tier II Exposure Studies: Study Design

Targeted Field Study (Field Residue Trial)

- Akin to a monitoring study
- Objective is to sample food sources relevant to bee exposures (*i.e.*, pollen and nectar) by quantifying pesticide residues in matrices relevant to bees
- Option to adapt study design of existing study requirement for pesticides in pollen and nectar (*e.g.*, Cropped TFD study)
- Sample timing is paramount (*e.g.*, sampling during bloom when bees should be foraging)
- Applicable scenarios include seed treatments, soil applications, and foliar sprays

Tier II Exposure Studies: Study Design

Semi-Field Tunnel Study

- Treated crop is kept under an enclosure (Tunnel) along with a nucleus hive of bees
- Pesticide concentrations can be quantified from the stomach contents, pollen sacs, pollen traps, and from hive matrices.
- Pollen and nectar could be sampled directly from the plant
- Applicable scenarios include seed treatments, soil applications, and foliar sprays

Tier II Exposure Studies: Design Considerations

- Application methods are variable
 - Target high-end exposure (maximum application)
- Crop selection must be relevant and attractive for bees
 - Systemic transport is chemical and crop dependent
 - Plants may have different matrices that represent food sources for bees (*e.g.*, corn vs. canola)
- Sampling design is paramount
 - Target maximum concentrations found in pollen and nectar
 - Sample pollen and nectar at different time points during bloom
 - Sampling to target crop and application method (*e.g.*, foliar applications sampled on day-0; soil applications and delayed transport)
- Climatic and regional variability

Questions?

EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products

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1 Executive Summary

Today, EPA is proposing additional mandatory pesticide label restrictions to protect managed bees under contract pollination services from foliar applications of pesticides that are acutely toxic to bees on a contact exposure basis. These restrictions would prohibit applications of pesticide products, which are acutely toxic to bees, during bloom where bees are known to be present under contract; these restrictions will apply to most insecticides and some herbicides. Today's proposed requirements would not supersede existing, more restrictive product use specifications.

EPA is also encouraging the efforts currently made by states and tribes to reduce pesticide exposures through development of locally-based measures. Specifically, EPA has been working with its state and tribal partners to develop Managed Pollinator Protection Plans (MP³s). Such plans were discussed in the June 2014, Presidential Memorandum¹ (the Memorandum or directive) and the National Strategy to Promote the Health of Honey Bees and Other Pollinators² (the Strategy) which identifies public/private partnerships as one means of addressing pollinator declines. These MP³s would include local and customizable mitigation measures to address certain scenarios that can result in exposure to pollinators. EPA will monitor the success of these plans in deciding whether further label restrictions are warranted.

Today's proposal addresses only acute exposure to pesticides from foliar applications under specific conditions. While the proposed mitigation focuses on managed bees under contract pollination services, EPA believes that in protecting managed bees in these circumstance, these measures would also protect native solitary and social bees that are also in and around treatment areas. Moreover, EPA recognizes there are concerns associated with potential exposure to chemicals that are not classified as acutely toxic by contact, including chemicals used in combination which may result in enhanced toxicity, and crops which incorporate pesticide residues in pollen/nectar. Future EPA actions will address these situations. EPA will continue to conduct chemical-specific risk assessments for bees and will consider additional product-specific mitigation as needed in the Office of Pesticide Program's (OPP's) registration and registration review programs.

Today's proposal, as well as EPA's support for development of state and tribal MP³s, is consistent with the President's directive and the National Strategy to Promote the Health of Honey Bees and Other Pollinators, which addresses the multiple factors affecting honey bees and pollinator health. The Strategy explains the need to expand federal efforts to reverse pollinator losses and calls for the development of new public-private partnerships across various sectors (state, tribal and local governments, industry, and non-governmental organizations) to reverse pollinator losses and restore populations to healthy levels.

¹ White House. 2014. Presidential Memorandum Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators. Memorandum for Heads of Executive Departments and Agencies. June 20, 2014. <http://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b>

² White House. 2015. National Strategy to Promote the Health of Honey Bees and Other Pollinators. May 19, 2015. <https://www.whitehouse.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf>

2 Background

EPA has taken steps, starting with the development of improved scientific tools to assess risks, to manage potential risks from pesticides to pollinators. EPA has routinely required toxicity tests with honey bees and has used these data as a surrogate for assessing risks to terrestrial invertebrates in general. In recent years there has been increasing uncertainty regarding whether these acute toxicity data are adequate to evaluate the role that pesticides play in pollinator declines. Consequently, EPA began to explore whether a broader suite of studies was needed to evaluate potential risks to bees. In response, EPA, Health Canada's Pest Management Regulatory Agency (PMRA), and the California Department of Pesticide Regulation (CDPR) developed a harmonized risk assessment framework that was presented to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in 2012³. After considering the SAP's advice, the EPA now has formalized its scientific process for quantifying potential risks to bees⁴. Data required for the risk assessment framework informs EPA risk assessors of the potential for adverse effects to individual bees, as well as bee colonies, from exposure that may result from the labeled use of a pesticide. This framework is now an integral part of the registration and registration review programs. Laboratory and field-based tests are also being developed for additional species of solitary and social bees^{5 6}.

Pesticide labels have routinely included bee advisory statements as outlined in 40 CFR 156.85(b)(5)⁷ and the Label Review Manual⁸ based on data from acute contact toxicity tests (*e.g.*, OCSPP Guideline 850.3020⁹) and studies on the toxicity of residues on foliage (OCSPP Test Guideline 850.3030¹⁰) using honey bees. The Directions for Use sections of the label of some products have also included more specific restrictions to protect pollinators, based on EPA's analysis of potential exposure and effects of the particular pesticide. However, stakeholders have continued to emphasize the need for greater clarity and stronger protections^{11 12}.

³ USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11 – 14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation http://www.epa.gov/oppead1/cb/csb_page/updates/2012/sapmtg-sept.html

⁴USEPA. 2014a. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

⁵ ICP-PR. 2012. Proceedings of the 11th International Symposium on the International Commission for Plant-Pollinator Relationships (ICP-PR) Bee Protection Group. Wageningen, Netherlands, November 2 – 4, 2011. Published in P.A. Oomen and H. Thompson eds, Julius Kühn Archiv 437.

⁶ ICP-PR. Proceedings of the International Commission for Plant-Pollinator Relationships (ICP-PR) Bee Protection Group 12th International Symposium Hazards on Pesticides to Bees. Ghent, Belgium. September 15 – 17, 2014. In preparation

⁷ CFR. 2014. Code of Federal Regulations. Title 40 (Protection of Environment), Chapter 1 (Environmental Protection Agency) Subchapter E (Pesticide Programs) Part 156 (Labeling Requirements for Pesticides and Devices) Subpart E (Environmental Hazard and Precautionary Statements) §156.85 (Non-target organisms) http://www.ecfr.gov/cgi-bin/text-idx?SID=511673be0c81c693acae95773c696225&node=se40.24.156_185&rgn=div8

⁸ USEPA. 2012. Label Review Manual. <http://www.epa.gov/oppead1/labeling/lrm/>

⁹ USEPA. 2012a. Ecological Effects Test Guidelines. OCSPP 850.3020 Honey Bee Acute Contact Toxicity. EPA 712-C-019. January 2012. http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series850.htm

¹⁰ USEPA. 2012b. Ecological Effects Test Guidelines OCSPP 850.3030 Honey Bee Toxicity of Residues on Foliage. EPA 712-C-018. January 2012. http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series850.htm

¹¹ USDA. 2013b. Report on the National Stakeholders Conference on Honey Bee Health. National Honey Bee Health Stakeholder Conference Steering Committee. October 17 – 17, 2012. <http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf>

¹² *Ibid* USEPA 2014b

In August 2013, EPA developed new label language for certain neonicotinoid insecticides¹³ in response to concerns from various stakeholder groups that these compounds represented a particular hazard to managed bees. At that time, EPA recognized that different exposure scenarios following foliar applications of the neonicotinoid pesticides warranted different degrees of mitigation. In one scenario (Scenario 1), large numbers of managed bees may be directly exposed to pesticide spray because they have been intentionally placed within or adjacent to the area being treated (*i.e.*, under a contract to pollinate a crop). In a second scenario (Scenario 2), managed bees may be directly exposed to pesticide spray via off-site pesticide drift, or because the bees are within forage range of the application area.

The label language developed¹⁴ for the neonicotinoid pesticides reflected the likelihood of different exposures for managed bees in Scenario 1 and Scenario 2. Given the intentional placement of colonies into or adjacent to the application area, the managed bees under contract pollination services (Scenario 1) are nearly certain to be exposed if an application is made. Consequently, to protect managed bees under contract pollination services at the application site, EPA prohibited application of neonicotinoid products while bees are foraging and until flowering is complete with the single exception of 48-hour notification to the beekeepers prior to foliar applications. For managed bees not under contract pollination services (Scenario 2), EPA prohibited application while bees are foraging and until flowering is complete but with more exceptions to enable growers and beekeepers to reduce potential exposure to bees while affording growers some flexibility to apply pesticides for crop protection. EPA concluded, consistent with the statutory mandate under FIFRA¹⁵, that these modifications of the neonicotinoid labels reduced the risks to bees in a manner that improved the overall balance of risks and benefits from using these pesticides.

Following issuance of the August 2013 letter¹⁶ directing label changes for neonicotinoid products, EPA announced its intention to follow a similar approach with other pesticides that are applied to the foliar surfaces of plants and are acutely toxic to bees on contact, *i.e.*, those pesticides with an acutely lethal dose to 50% of the bees tested (abbreviated LD₅₀) of less than 11 micrograms per bee (<11 µg/bee), based on either the acute contact toxicity test following OCSPP Guideline 850.3020¹⁷ or its equivalent test in Europe (*i.e.*, OECD 214¹⁸). These acute toxicity data, which have been routinely required for pesticides, are frequently corroborated with bee kill incident data reported to EPA. The use of incident

¹³ Neonicotinoids are a class of insecticides with a common mode of action that affects the central nervous system of insects, causing paralysis and death.

¹⁴ USEPA. 2014c. New Labeling for Neonicotinoid Pesticides. <http://www2.epa.gov/pollinator-protection/new-labeling-neonicotinoid-pesticides>

¹⁵ The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides federal control of pesticide distribution, sale and use. All pesticides used in the United States must be registered (licensed) by EPA. For more information, see: <http://www.epa.gov/agriculture/lfra.html>

¹⁶ USEPA. 2013c. Memorandum to Registrants of Neonicotinoid Products on Pollinator Protection Labeling for nitroguanidine neonicotinoid products. <http://www2.epa.gov/sites/production/files/2013-11/documents/bee-label-info-ltr.pdf>

¹⁷ *Ibid* USEPA. 2012a.

¹⁸ OECD. 1998. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. http://www.oecd-ilibrary.org/environment/test-no-214-honey-bees-acute-contact-toxicity-test_9789264070189-en;jsessionid=43gvto47wnue9.delta

data as a line of evidence in evaluating the potential risks associated with pesticides is discussed in associated guidance documents^{19 20 21 22}.

3 Problem Statement

Pesticides, particularly those intended to control insect pests, can harm bees. Pesticides have also been identified as one among multiple factors negatively impacting pollinator health, including declines in honey bees specifically^{23 24}. Through discussions with various stakeholders and based on reported bee kill incidents contained within the EPA Incident Data System (IDS) and the Ecological Incident Information System (EIIIS) databases for a large number of pesticides that have been classified as moderately or highly toxic to bees on an acute exposure basis, EPA has concluded that additional measures would provide better protection for bees from acute contact exposures. EPA is also aware that there are often inadequate relationships and a lack of suitable communication mechanisms in place at the local level between and among beekeepers, growers, and pesticide applicators to assure that pesticides needed to protect crops can be applied in ways that are not harmful to bees. Therefore, clearer and more consistent mandatory label restrictions could reduce the potential exposure to bees from pesticides categorized as acutely toxic to bees, *i.e.*, those compounds with an acute contact LD₅₀<11 µg/bee, in situations where large numbers of managed bees are intentionally positioned under contract in or close to pesticide application sites. In addition, EPA believes that state and tribal managed pollinator protection plans provide a means of developing localized and customized mitigation measures to reduce exposure of bees to pesticides in certain scenarios.

4 Desired State

A common theme from discussions about pesticides and pollinators with one of EPA's federal advisory committees, the Pesticide Program Dialogue Committee (PPDC)²⁵, and with other stakeholder groups²⁶ has been the need for clearer communications between growers/applicators, beekeepers and enforcement authorities. Stakeholders have indicated that more direct lines of communication are

¹⁹ USEPA 2011. Memorandum from Donald J. Brady, Director on Guidance for Using Incident Data in Evaluating Listed and Non-listed Species under Registration Review. http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/terrestrial_biology_tech_team/honeybee_data_interim_guidance.pdf

²⁰ *Ibid* USEPA 2004

²¹ *Ibid* USEPA 2012

²² *Ibid* USEPA 2014a

²³ *Ibid* USDA 2013

²⁴ vanEngelsdorp, D., J. D. Evans, C. Saegerman, C. Mullin, E. Haubruge, B. K. Nguyen, M. Frazier, J. Frazier, D. Cox-Foster, Y. Chen, R. Underwood, D. R. Tarpy, J. S. Pettis. 2009. Colony Collapse Disorder: A Descriptive Study. PLoS ONE 4(8): e6481.

Doi:10.1371/journal.pone.0006481 <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0006481>

²⁵ A description of the USEPA Pesticide Program Dialogue Committee Pollinator Protection Workgroup can be found at <http://www2.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee>

²⁶ *Ibid* USDA. 2013b.

needed at the local level. Groups such as the State FIFRA Issues Research and Evaluation Group (SFIREG²⁷) have echoed these concerns.

As directed by the Presidential Memorandum and described in the Strategy, EPA is working with states and tribes to increase the communication among all local stakeholders that have a part in protecting bees from exposure to pesticides and to promote implementation of integrated pest management (IPM²⁸). The EPA sees collaboration on Managed Pollinator Protection Plans (MP³s) as a means to enhance communication and risk mitigation. The purpose of an MP³ with respect to pesticide use is to utilize local expertise to identify customizable solutions to effectively mitigate risk from acutely toxic pesticides to managed bees²⁹.

EPA is aware of concerns that approaches to assess and mitigate risk to managed honey bees may not be protective of unmanaged bees (*i.e.*, “native” or “wild” bees). EPA’s ecological risk assessment framework documents^{30 31 32}, discuss the uncertainties associated with the use of surrogate species (*e.g.*, the use of the honey bee) for determining the potential for adverse effects to untested insect pollinator species as a result of exposure to pesticides. Using the honey bee as a surrogate species is consistent with both its established use in risk assessment and the currently available science. EPA believes that the approach taken to protect managed honey bees will also decrease the risks to wild bees since pesticides are generally likely to affect wild bees and managed bees in a similar manner. Moreover, EPA believes that additional measures to protect managed bees will provide protections to other pollinators as well. For example, measures designed to ensure that applications are only made when managed bees are not likely to be foraging will also be effective for other pollinators with similar foraging behavior and will reduce potential exposure to wild bees as well. This effort is also consistent with the Presidential directive and the Strategy which seeks to promote the health of honey bees and other pollinators to *“ensure the sustainability of our food production systems, avoid additional economic impact on the agricultural sector and protect the health of the environment.”*³³

²⁷ The State FIFRA Issues Research and Evaluation Group (SFIREG) is comprised of State, Federal, Tribal and Association representatives, and meets periodically to identify and discuss issues related to pesticides that affect the states/tribes. A description of SFIREG can be found at the following link: <http://www.aapco.org/sfireg.html>

²⁸ Integrated Pest Management (IPM) programs use current, comprehensive information on the life cycles of pests and their interaction with the environment. This information in combination with available pest control methods, is used to manage pest damage by the most economical means while minimizing potential hazards to people, property and the environment.

²⁹ Managed bees include those for purposes of pollination services and honey production (*i.e.*, honey bees, bumble bees, alfalfa leaf cutters, and blue orchard bees). Managed bees may be managed by hobbyists or commercial beekeepers.

³⁰ *Ibid* USEPA 2004

³¹ *Ibid* USEPA 2012

³² *Ibid* USEPA 2014a

³³ *Ibid* White House. 2014

Over the last few years, several states, such as California³⁴ ³⁵, Colorado³⁶, Florida³⁷, Mississippi³⁸, North Dakota³⁹ and others, have independently developed state-specific pollinator protection plans to enhance communication between stakeholders (*e.g.*, beekeepers, growers, applicators) which in turn is intended to reduce the potential exposure to bees from pesticides. In some cases, states have completed rule-making (*e.g.*, Iowa⁴⁰ and California⁴¹) which has established mandatory mitigation measures where beekeepers must be notified in advance of applications or applications may not take place during times when bees are likely to be foraging on the treated crop. These states have developed these plans in response to the needs of the growers and beekeepers of their states. The plans are aimed at identifying measures to mitigate potential exposure to bees from pesticides while providing flexibility to growers and beekeepers. A common element of each of the plans has been that they are founded on stakeholder engagement and consensus building; therefore, the state pollinator plans foster communication and collaboration between growers and the beekeepers. Feedback from state lead agencies, which have developed pollinator protection plans, indicates that the plans have been effective in increasing communication and mitigating risk. This result is evident from decreased numbers of bee kill incident reports, an increase in the number of bee hives registered in apiary registries, and an increased number of requests for advice when landowners cannot reach beekeepers. Although there are areas of commonality in the state-specific plans, they take many different approaches, since each reflects local conditions and local solutions.

One element of the Strategy is for EPA to engage with states and tribes and others on the development of pollinator protection plans. EPA's initial discussions about pollinator protection plans have been with co-regulators through the SFIREG, the Association of American Pesticide Control Officials (AAPCO⁴²) and the Tribal Pesticide Program Council (TPPC). These discussions have led to the realization that additional guidance is needed for states and tribes in the development of such plans, and state lead agencies are developing such guidance. As discussed in section 5.3.1, a draft guidance document has been circulated for wider review by states and will be made available following incorporation of their feedback.

5 Proposed Mitigation Approach and Rationale

EPA is proposing label changes to provide additional protections to managed bees under contract pollination services and is encouraging local solutions in the form of state and tribal MP³s for managed

³⁴ California Department of Food and Agriculture. 2014. Bee and Beehive Information.

<http://www.cdffa.ca.gov/plant/PE/interiorexclusion/bees.html>

³⁵ California Food and Agricultural Code Section 29040-29056 <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fac&group=29001-30000&file=29040-29056>

³⁶ Colorado Environmental Pesticide Education Program. Pollinator Protection 2013.

<http://www.cepep.colostate.edu/Pollinator%20Protection/index.html>

³⁷ Florida Department of Agriculture and Consumer Services. 2014. Florida Bee Protection. <http://www.freshfromflorida.com/Divisions-Offices/Agricultural-Environmental-Services/Consumer-Resources/Florida-Bee-Protection>

³⁸ Mississippi Honeybee Stewardship Program. 2014 http://www.msfb.org/public_policy/Resource%20pdfs/Bee%20Brochure.pdf

³⁹ North Dakota Department of Agriculture. 2014. North Dakota Pollinator Plan. A North Dakota Department of Agriculture Publication. <http://www.nd.gov/ndda/files/resource/NorthDakotaPollinatorPlan2014.pdf>

⁴⁰ Iowa Department of Agriculture. Advancing Iowa's Agricultural Interests. See Iowa Administrative Code Chapter 21-45.31(206).

http://www.iowaagriculture.gov/horticulture_and_farmersmarkets/sensitivecropdirectory.asp

⁴¹ California Department of Pesticide Regulation. Food and Agriculture Code Section 29040-29056. <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fac&group=29001-30000&file=29040-29056>

⁴² AAPCO. 2014. Association of American Pesticide Control Officials. <http://www.aapco.org/>

bees not under contract services. EPA will work with state and tribal lead agencies to facilitate adoption of and compliance with MP³s that reflect public stakeholder processes. EPA will monitor the success of these plans in mitigating risk to bees from acutely toxic pesticides on an ongoing basis and determine whether additional EPA action is warranted. In the following section, the scope of these changes is discussed.

5.1 General Approach

EPA continues to believe that bees are likely to be exposed from application of acutely toxic pesticides, although the certainty such exposure will occur differs in ways that warrant different approaches to risk mitigation. When managed bees are on site under contract to pollinate the crop, which can also be the application area, relatively large numbers of bees are intentionally placed in or near the crop area, *i.e.*, managed bees are a direct input to the production of the crop. Consequently, large numbers of bees are likely to be directly exposed to pesticide spray during a pesticide application. Underscoring the potential magnitude of colonies that may be present at an application site requiring contracted pollination services, the EIS database contains reports from commercial beekeepers of adverse effects to roughly 20,000 colonies contracted to support pollination services in almonds and roughly 2,000 colonies contracted to support pollination services in blueberries purportedly due to pesticide applications made while large numbers of colonies were in or near treatment areas in 2014 alone. In addition, EPA has heard claims of tens of thousands more colonies in almonds and blueberries being affected in 2014. (EPA notes, however, that it is not clear whether these adverse effects were acute or chronic with respect to the timing of pesticide applications relative to when bees may have been actively foraging, since those incidents have not been formally reported to EPA and/or investigated by state lead agencies responsible for enforcing compliance with pesticide label restrictions.) Although the EIS contains numerous bee kill incident reports from beekeepers who were not providing contracted pollinations services at the time of the incident, those individual reports have not been of similar magnitude (*i.e.*, simultaneously impacting thousands of hives) as those reported by commercial beekeepers providing contracted pollinator services.

When managed bees are not providing pollination services at a site that is being treated with a pesticide, they may still be directly exposed because the application site is within forage range of those bees. In such circumstances, EPA considers the likelihood of exposure to large numbers of managed bees to be somewhat lower since large numbers of colonies are not intentionally placed within or near the treatment area. EPA believes that the likelihood of exposure between the two scenarios is significantly different and that, given their proximity to the treated crop, large numbers of managed bees under contract pollination services are nearly certain to be exposed and potentially adversely affected if an application with an acutely toxic pesticide is made. Further, in evaluating these two scenarios (where bees are brought on site under contract vs. when bees may be present but the grower may not derive a benefit from the presence of bees on his or her property), EPA believes it is also appropriate to consider the benefit or lack of benefit that bees are providing to the grower in determining the nature and scope of mitigation. Consequently, EPA is proposing different mitigation approaches for these two scenarios; however, EPA will continue to evaluate the efficacy of these efforts to determine whether additional action is needed.

The proposed restrictions outlined in the following sections would not replace more restrictive chemical-specific, bee-protective provisions (*e.g.*, pre-bloom restrictions) that may already be on a product label. For example, based on chemical-specific assessment, EPA may have determined that the persistence of toxic residues in pollen and nectar requires that an application be prohibited for a period of time prior to bloom, in addition to prohibitions during bloom, in order to ensure that residues in pollen and nectar be below levels of concern when bees are likely to be exposed (*i.e.*, a pre-bloom restriction). These more restrictive prohibitions would not be superseded by the proposed mitigation described below. As discussed previously, EPA will continue to conduct comprehensive chemical-specific risk evaluations and take appropriate action to further mitigate identified risks through the registration and registration review programs based on the available science.

5.2 Application to sites with bees present under contract for pollination services

As discussed above, contracted pollination services result in a heightened exposure potential where a large number of honey bee colonies are intentionally placed at a use site, and the application of a toxic pesticide in this scenario is nearly certain to result in adverse effects to pollinators. Although the likely outcomes are counter-productive for both the beekeeper (loss of honey bee stock) and the grower (diminished pollination services), many beekeepers and growers have not found ways to avoid such outcomes. Consequently, EPA believes that strong regulatory measures should be in place for the contracted service scenario to mitigate these potential problems. Therefore, EPA proposes the following:

- To prohibit the foliar application of acutely toxic products during bloom for sites with bees on-site under contract, unless the application is made in accordance with a government-declared public health response. (See proposed label language in **Appendix B.**)

There would be no other exceptions to the bloom prohibition in the contracted-services scenario. Current neonicotinoid product labels include a 48-hr notification exception to the bloom prohibition. However, as part of this mitigation proposal, the 48-hr notification exception for crops under contracted pollination services during bloom for all neonicotinoid product labels would be removed.

The proposed mitigation applies to all products (FIFRA Section 3 and 24(c) Special Local Need registrations and where applicable Section 18 emergency exemption petitions*) that have:

- (1) liquid or dust formulations as applied; and,
- (2) foliar use directions for use on agricultural crops with bees onsite under contract for pollination services; and,
- (3) active ingredient(s) that have been determined via testing to have an acute contact toxicity value less than 11 micrograms per bee ($LD_{50} < 11 \mu\text{g}/\text{bee}$). The active ingredients that meet this criterion are listed in Appendix A. EPA will also consider as a line of evidence those active ingredients that have resulted in bee kill incidents that were investigated and determined to result from the proper use (*i.e.*, were not the result of a misuse) of a product.

*depending on the nature of the emergency for which a Section 18 petition has been submitted, the at-bloom restriction may not apply. This determination will be reached on a case-by-case evaluation.

The mitigation measures proposed for when bees are present under contract pollination would not apply to applications made in support of public health such as use for wide area mosquito control. EPA recognizes that a wide area mosquito control application can impact large numbers of bees if the application co-occurs in areas with pollinator-attractive plants; however, such applications utilizing products classified as acutely toxic to bees are used to protect public health through mosquito abatement.

Also, EPA encourages pollination service contracts established between growers and beekeepers that take into account the increased likelihood of bee colony exposure by including provisions to ensure that colonies will be protected and pollination services secured. If EPA receives evidence during the public comment period and/or through outreach at stakeholder meetings that such contract provisions are common or that there are other effective and mutually agreed upon stakeholder (*i.e.*, beekeeper-to-grower) practices indicating that application of acutely toxic pesticides is not of risk concern for bees under contract, then EPA will consider this evidence in determining whether this scenario needs the mitigation indicated in the proposed language.

5.3 Application to sites that are not under contracted pollination services

EPA believes that managed bees not under contracted services (and other unmanaged bees) may also be exposed to acutely toxic pesticides when they are within forage range of the application site. While pesticide exposure under this scenario is possible, it is less certain than in situations where a pesticide is applied to a site when large numbers of managed bees have intentionally been positioned at the site for the purposes of providing pollination services. EPA believes that the lower likelihood of exposure for large numbers of managed bees in this scenario may warrant, in the future, a more flexible approach toward mitigation such as that afforded by state or tribal Managed Pollinator Protection Plans (MP³s). Further, feedback provided by multiple stakeholders (including growers, applicators, beekeepers, and state lead agencies) indicates that there is a wide range of local conditions which militate against a single regulatory approach to providing protections for non-contracted managed bees. Many, however, have recognized that the success of pollinator protection efforts will depend on clear communication among affected stakeholders to design effective, localized approaches.

Accordingly, EPA will encourage states and tribes to develop MP³s that are effective in reducing the likelihood of bees being present in the treatment area at the time a pesticide application is to be made. EPA will work with state and tribal lead agencies to facilitate adoption of and compliance with MP³s that reflect local agronomic practices. This can be best achieved through state or tribal MP³s which results from a public stakeholder process. EPA will monitor success of these MP³s in mitigating risk to bees from acutely toxic pesticides on an ongoing basis and determine whether additional EPA action is warranted. Therefore, for managed bees not under contract pollination services, no further changes to product labels, including the neonicotinoid pesticides, are proposed at this time.

5.3.1 State and Tribal Managed Pollinator Protection Plans (MP³s)

Through discussions with the PPDC, AAPCO, and SFIREG, EPA recognizes that several states (*e.g.*, California^{43 44}, Colorado⁴⁵, Florida⁴⁶, Mississippi⁴⁷, and North Dakota⁴⁸) have developed MP³s by productively engaging stakeholders within their respective states. These plans serve as examples of effective collaboration between stakeholders at the local level that can lead to broader awareness of needs and increased cooperation between stakeholders to reduce pesticide exposure for bees while maintaining the flexibility to protect crops. The common element in these plans has been the increased communication between stakeholders, and anecdotal reports from the stakeholder groups suggest that the plans are effective at increasing communication and cooperation.

The EPA is generally promoting the development of state and tribal MP³s that cover use of acutely toxic pesticides sites where there are no bees onsite under contract pollination services; however, the scope of such plans is not limited to a specific scenario. States and tribes have the flexibility to determine the scope of an MP³ that best responds to pollinator issues in their region. For example, the scope could include applications to crops, and commercial applications to ornamentals in commercial, public, and residential settings, and other scenarios.

SFIREG has drafted guidance for states to consider in developing MP³s, which identifies several elements for establishing a framework for communication and cooperation between beekeepers and growers and reducing pesticide exposure for managed bees. Tribes are also encouraged to consider this guidance in developing their own MP³s, as appropriate. In general, these elements include a public stakeholder participation process for the development of a MP³ to encourage local solutions based on improved communication and cooperation; a method for growers/applicators to know if there are managed bees near treatment sites, and to identify and contact beekeepers prior to application that will enable the grower/applicator to communicate about any planned treatments and how best to protect the colonies; inclusion of best management practices that both the grower/applicator and beekeeper can undertake to limit exposure of the managed bees to the proposed pesticide application; a clear defined plan for public outreach to promote robust adoption of the plan; a process to periodically review and modify the plan as needed; and a mechanism to measure the effectiveness of the managed pollinator protection plan. In addition, other recommendations are included in the guidance document for consideration in developing MP³s. This draft guidance document has been circulated by SFIREG for wider review by states and is, therefore, subject to change. The final guidance document is expected to be made available following incorporation of their feedback.

While EPA's proposed label statement would address risks to managed bees present at a site under contract for pollination services, state and tribal MP³s may address pesticide-related risks to all pollinators, including managed bees, whether or not they are present under a contract, as well as wild pollinators. As noted earlier though, the scope of state and tribal MP³s is not limited to a particular

⁴³ California Department of Food and Agriculture. 2014. Bee and Beehive Information. <http://www.cdffa.ca.gov/plant/pollinators/index.html>

⁴⁴ California Food and Agricultural Code Section 29040-29056 <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fac&group=29001-30000&file=29040-29056>

⁴⁵ Colorado Environmental Pesticide Education Program. Pollinator Protection 2013. <http://www.cepep.colostate.edu/Pollinator%20Protection/index.html>

⁴⁶ *Ibid* Florida Department of Agriculture and Consumer Services. 2014.

⁴⁷ *Ibid* Mississippi Honeybee Stewardship Program. 2014.

⁴⁸ *Ibid* North Dakota Department of Agriculture. 2014.

scenario for managed bees nor would such plans be limited to agricultural practices but could extend to a broader number of pollinating species and habitats. EPA has worked collaboratively with the U.S. Department of Agriculture and Michigan State University, as well as consulted published sources^{49 50 51}, to identify plants that are pollinator attractive and which require managed pollination services. The list of pollinator-attractive plants is based in part on those plants contained in the European Food Safety Authority (EFSA) guidance for assessing risks of pesticides to bees⁵²; however, USDA has included a broader number of plant species in its assessment and has provided references to support the attractiveness classification. Based on the list, most crops categorized as attractive to native bees are attractive to honey bees as well; EPA recognizes that there are exceptions (*e.g.*, tomatoes). States and tribes are encouraged to consider this list of pollinator-attractive plants when it becomes available for developing their MP³s.

6 Uncertainties

While the intent of the proposed label changes and state and tribal MP³s is to reduce exposure of managed bees to pesticides that are acutely toxic on contact, uncertainties remain regarding chemicals that may not fall within the domain of the proposal. These uncertainties are discussed below.

6.1 Non-acutely toxic insecticides and insect growth regulators

EPA recognizes that in addition to causing acute lethal effects, pesticides may cause sublethal chronic effects and effects to insect pollinators at various life stages and at various levels of biological organization (individual and colony-level). Specifically, non-acutely toxic insecticides such as insect growth regulators (IGRs) generally target early developmental stages (*e.g.*, larvae, pupae) and have varying degrees of specificity to target pest species. The determination of whether or not a specific IGR will have activity on honey bees and non-*Apis* pollinator species needs to be made on a chemical-specific basis. For example, EPA has a full suite of effects data for methoxyfenozide, a chemical which mimics the molting hormone ecdysone, and these data show that the chemical does not adversely affect larval and adult honey bees, either at the individual level or at the whole colony level. However, there are preliminary data for other IGRs (*e.g.*, diflubenzuron) which suggest possible adverse effects to honey bee larval and pupal development. As discussed previously, to address these concerns, EPA will continue to require a suite of effects and residue studies, conduct comprehensive chemical-specific risk evaluations according to the *Guidance for Assessing Pesticide Risks to Bees*,⁵³ and take appropriate action to further mitigate identified risks through the registration and registration review programs based on the available science.

⁴⁹ McGregor SE, 1976. Insect pollination of cultivated crop plants. Agricultural Handbook No. 496. Ed USDA Agricultural Research Service W, D.C, USA.

⁵⁰ Free JB. 1993. Insect Pollination of crops, 2nd edn. Academic Press: London, UK.

⁵¹ Delaplane, K. S. & Mayer, D. F. (2000). Crop Pollination by Bees. – New York, Oxon (CABI Publishing).

⁵² European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). Appendix D. EFSA Journal 2013; 11(7):3295, 266 pp., doi: 10.2903/j.efsa.2013.3295.

⁵³ *Ibid* USEPA 2014

6.2 Insect Growth Regulators and Fungicide Tank Mixes

EPA is also aware of concerns regarding the potential effects to honey bee larvae and queen development reported in connection with bee incidents following tank mixed applications of certain fungicides with insecticides (including IGRs that are not acutely toxic to adult bees). Field reports from beekeepers allege that applications of these tank mixes during almond bloom are having colony-level effects. However, there are also beekeepers reporting little to no effects on bees located close to the sites of tank-mixed applications in question. Additionally, EPA is aware of research that is being conducted to quantify the level of interaction between some IGRs and some fungicides^{54 55}. The research to date is limited and specific to diflubenzuron (Dimilin®) and a subset of fungicides (*e.g.*, boscalid and pyraclostrobin (Pristine®)), but this research has shown no synergistic effects at environmentally relevant concentrations. Additional research to evaluate the interaction between Dimilin® and other fungicides (*e.g.*, propiconazole, Tilt® and iprodione, Roval®) and other IGRs (*e.g.*, methoxyfenozide, Intrepid®) at environmentally relevant concentrations is underway⁵⁶. EPA will continue to evaluate the open literature as part of the registration and registration review programs and may require additional testing on specific IGR-fungicide combinations to address specific uncertainties identified in the open literature and through reported incidents. Additionally, EPA requests that additional scientific information regarding the effects of tank-mixed IGRs and fungicides be submitted in response to this proposal.

6.3 Systemic Pesticides and Prolonged Residual Toxicity

EPA recognizes the concern surrounding systemic pesticides and those with prolonged residual toxicity. Systemic pesticides that have prolonged residual toxicity may not be adequately addressed by the proposed mitigation discussed in this proposal. When applied using methods other than foliar treatments (*e.g.*, soil, seed treatment, and tree injection applications), systemic pesticides and/or pesticides with prolonged residual toxicity may result in residues in pollen and nectar at levels that can impact bees and hive health. However, the likelihood of this occurring is highly dependent on the specific properties of the pesticide (*i.e.*, the degree to which the pesticide is transported in the plant, the persistence of the pesticide residues, and the levels at which lethal and non-lethal effects occur). As discussed previously, to address these concerns, EPA will continue to require a suite of effects and residue studies, conduct comprehensive chemical-specific risk evaluations according to the Guidance for Assessing Pesticide Risks to Bees⁵⁷, and take appropriate action to further mitigate identified risks through the registration and registration review programs based on the available science.

6.4 Indeterminate Bloom

EPA understands that there are some flowering crops and ornamentals that have an indeterminate period of bloom, *i.e.*, these crops flower, set fruit and continue to flower throughout the year, and that for these crops bees are present under contract for pollination services for extended periods of time. Examples of indeterminate blooming crops which involve commercial pollination services include: cucurbits, strawberries, *etc.* EPA recognizes that the proposed prohibition on application of acutely toxic pesticides during the time when bees are present under contract may cause significant issues for

⁵⁴ DeGrandi-Hoffmann, G., Y. Chen and R. Simonds. 2013. The Effects of Pesticides on Queen Rearing and Virus Titers in Honey Bees (*Apis mellifera* L.). *Insects* 4(1): 71 – 89 doi 10.3390/insects4010071

⁵⁵ Johnson, R. M. and E. Percel. 2012. Pristine Effects on Queen Rearing Process. Final report to Project Apis m.

⁵⁶ Johnson, R.M., E.G. Purcell. 2013. "Effect of 'Bee-Safe' Insecticides and Fungicides on Honey Bee Queen Development and Survival." Poster presented at 2nd International Conference on Pollinator Biology, Health and Policy, Aug. 14–17, 2013, Pennsylvania State University.

⁵⁷ *Ibid* USEPA 2014

the growers of these crops. Therefore, EPA requests input during the comment period on alternative mitigation approaches for these pollinator-attractive crops with indeterminate periods of bloom.

6.5 Microbial Pesticides

EPA recognizes that microbial pesticide toxicity values are not typically expressed in terms of micrograms per bee or determined from contact exposure which is typically seen with conventional pesticides. However, the mitigation measures/approach described in this proposal may be appropriate for microbial products that are acutely toxic or pathogenic to bees. Before determining whether mitigation would be appropriate for any microbial pesticide, EPA would need to evaluate whether the honeybee toxicity/pathogenicity studies it receives for microbial pesticides can yield some equivalent information about acute toxicity that is presented by the contact toxicity tests done for conventional chemicals. If not, EPA would need to determine whether additional data are needed to more fully evaluate microbial pesticides' risks to bees, and what regulatory triggers are appropriate for determining the need for this proposed mitigation. These data and resulting triggers might vary based on factors such as the type of microbial pesticide (e.g., insect pathogens, live microbes, killed microbes) and expected routes of exposure.

7 Implementation

Proposed label language that reflect the prohibition of foliar application of acutely toxic products during bloom for sites with bees on-site under contract is provided in Appendix B. Instructions to registrants are to be developed that will describe the specific changes that are to be made to product labels that are consistent with these changes, including the select neonicotinoid products labels that were previously modified to reduce risks to bees.

8 Summary

As discussed in this paper and consistent with previous actions by the EPA and the Strategy, EPA is proposing additional restrictions for pesticide applications to blooming crops where managed bees are present under a contract, for pesticides that are acutely toxic to bees (*i.e.*, those chemicals with an acute contact $LD_{50} < 11 \mu\text{g}/\text{bee}$). For applications of acutely toxic pesticides at bloom where bees may be present other than from contracted pollination, EPA is expecting the development of state and tribal managed MP³s contoured to reflect local needs and conditions to address exposure of managed bees in non-contracted scenarios. EPA will be evaluating on an ongoing basis the effectiveness of these plans at reducing exposure of bees to pesticides. After state or tribal MP³s have been in place for several years, EPA will then determine whether additional label revisions are appropriate. These actions are intended to reduce the likelihood of acute exposure of honey bees following application of acutely toxic pesticides. In being protective for managed honey bees, these actions are believed to be protective for other solitary and social bees and other pollinators that may be at or near the application site at bloom.

The Agency has relied on multiple lines of evidence (*e.g.*, acute toxicity studies as well as bee kill incident data when available) to support its understanding of the acute exposure to and toxicity of the pesticides in question. The proposed mandatory language in the Directions for Use is based on the available science and the expectation that larger numbers of bees will be present in or near application sites under contracted pollination services. The proposed mitigation is intended to enhance pollinator protection for particular application scenarios and is not intended to supersede more restrictive

product-specific use prohibitions. Through both the registration and registration review programs, EPA will continue to conduct chemical-specific risk assessment for bees that will address other potential routes of exposure (*e.g.*, ingestion of pesticide residues in pollen and nectar) and other potential effects (*e.g.*, chronic effects) and will consider additional, appropriate product-specific mitigation as needed.

Appendix A – List of registered active ingredients that meet the acute toxicity criteria

Abamectin	Dicrotophos	Momfluorothrin
Acephate	Dimethoate	Naled
Acetamiprid	Dinotefuran	Oxamyl
Aldicarb	Diuron	Permethrin
Alpha-cypermethrin	D-trans-allevthrin	Phenothrin
Amitraz	Emamectin benzoate	Phorate
Arsenic acid	Endosulfan	Phosmet
Azadirachtin	Esfenvalerate	Pirimiphos-methyl
Bensulide	Ethoprop	Prallethrin
Beta-cyfluthrin	Etofenprox	Profenofos
Bifenthrin	Fenazaquin	Propoxur
Carbaryl	Fenitrothion	Pyrethrins
Carbofuran	Fenpropathrin	Pyridaben
Chlorethoxyfos	Fipronil	Resmethrin
Chlorfenapyr	Fluvalinate	Rotenone
Chlorpyrifos	Fosthiazate	Sethoxydim
Chlorpyrifos methyl	Gamma-cyhalothrin	Spinetoram
Clothianidin	Imidacloprid	Spinosad
Cyantraniliprole	Imiprothrin	Sulfoxaflor
Cyfluthrin	Indoxacarb	Tefluthrin
Cypermethrin	Lambda-cyhalothrin	Tetrachlorvinphos
Cyphenothrin	Malathion	Tetramethrin
Deltamethrin	Metaflumizone	Thiamethoxam
Diazinon	Methiocarb	Tolfenpyrad
Dichlorvos	Methomyl	Zeta-cypermethrin

Appendix B – Proposed Labeling

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR FOLIAR APPLICATIONS OF THIS PRODUCT TO SITES WITH BEES ON-SITE FOR COMMERCIAL POLLINATION SERVICES: Foliar application of this product is prohibited from onset of flowering until flowering is complete when bees are on-site under contract, unless the application is made in association with a government-declared public health response. If site-specific pollinator protection/pre-bloom restrictions exist, then those restrictions must also be followed.